

IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE:
NATIONAL PRESCRIPTION
OPIATE LITIGATION

Case No. 1:17-md-2804
Cleveland, Ohio

CASE TRACK THREE

October 12, 2021
9:00 a.m.

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VOLUME 6

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TRANSCRIPT OF JURY TRIAL PROCEEDINGS,
BEFORE THE HONORABLE DAN A. POLSTER,
UNITED STATES DISTRICT JUDGE,
AND A JURY.

- - - - -

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1 TUESDAY, OCTOBER 12, 2021, 9:03 A.M.

2 THE COURT: All right. Good morning.

3 Everyone be seated.

4 I think the witness could come up.

09:05:34 5 (Jury in.)

6 THE COURT: Okay. Please be seated.

7 Good morning, ladies and gentlemen. I hope

8 you all had a good weekend so we're going to continue

9 with Mr. Catizone's testimony, and, sir, I'd like to

09:06:10 10 remind you you're still under oath from last week.

11 Mr. Swanson.

12 MR. SWANSON: Good morning, Your Honor.

13 Good morning.

14 Your Honor, over the weekend I put together

09:06:21 15 just a few documents I'd like to use.

16 May I approach the witness?

17 THE COURT: Yes.

18 MR. SWANSON: So I can hand it to him.

19 I'll go over the top.

09:06:33 20 THE WITNESS: Thank you, sir.

21 MR. SWANSON: Thank you.

22 CROSS-EXAMINATION OF CARMEN CATIZONE (RESUMED)

23 BY MR. SWANSON:

24 Q. Good morning, Mr. Catizone. How are you today?

09:06:51 25 A. Fine, sir. Yourself?

1 Q. Well. Thank you for asking.

2 Again, I'm Brian Swanson, I represent
3 Walgreen's.

4 What I wanted to do to start off this
09:07:02 5 morning is to pick up where we left off, and that was
6 talking about the stakeholders document that your
7 organization, former organization, the NABP, created with
8 input from the DEA and the chain pharmacies and others.

9 Okay?

09:07:21 10 A. Yes, sir.

11 Q. Okay. So what I'm going to do is call up a
12 document.

13 Okay. So, Mr. Catizone, I've given you a
14 hard copy of the document. It's behind Tab 1. And then
09:07:45 15 I've also put the document up on the screen, so whichever
16 is easier for you to follow along, feel free.

17 A. Thank you.

18 Q. Do you recognize what's been marked as Defendants'
19 MDL Exhibit 11427?

09:07:59 20 A. Yes, sir.

21 Q. Is this the stakeholders document that you put
22 together when you were at the NABP?

23 A. Yes, sir.

24 Q. And it's several pages and I'm not going to talk
09:08:12 25 about every page, but I do want to ask you about a few of

1 them.

2 If you look at the executive summary there,
3 I think I asked you on Friday, but I just wanted to
4 confirm, this project, putting together this document, it
09:08:28 5 began in 2013.

6 Is that true?

7 A. Yes, sir.

8 Q. And it looks like, if you can see in the first
9 paragraph, it was October of 2013.

09:08:43 10 Did I highlight it there? Do you see that?

11 A. Yes, sir.

12 Q. Okay. And so that was when you were approached by
13 Walgreen's and the AMA?

14 A. No, sir. We were approached prior to that. That
09:08:53 15 was the first meeting of the group.

16 Q. I see. So they had come to the organization before
17 that and October, '13 is when the team got together?

18 A. Yes, sir.

19 Q. Okay. If you could flip, please, to Page 7.

09:09:12 20 I want to ask you about this second
21 paragraph here. Trying to call it up.

22 Okay. Do you see the paragraph I'm looking
23 at there I have blown up on the screen?

24 A. Yes, sir.

09:09:28 25 Q. Okay. It says, "During the past two decades,

1 growing numbers of patients with persistent noncancer
2 pain have been offered long-term opioid therapy. This
3 change in prescribing behavior has been influenced by
4 several competing interests."

09:09:47 5 Do you see that?

6 A. Yes, sir.

7 Q. Okay. And that was -- that was the view of the DEA
8 and the NABP and everyone involved in this document.

9 True?

09:09:56 10 A. No, sir.

11 Q. Okay. Is that the document that or is that the
12 language that went into the document the organization put
13 out?

14 A. That was the language submitted by the prescribers
09:10:07 15 based upon their position that others then deferred to
16 the prescribers to say that's what the prescribers are
17 finding, and others simply signed off on the document
18 summary and the conclusions at the end, sir.

19 Q. I see. So the prescribers were explaining to the
09:10:24 20 rest of the group what they were seeing in the evolving
21 standard of care, is that fair?

22 A. Exactly, sir.

23 Q. Okay. Thank you.

24 If you look on a bit further in there, you
09:10:34 25 see that it talks about, "In both hospital and outpatient

1 settings, the recognition of pain as the fifth vital
2 sign, and the evolution of patient satisfaction surveys
3 that include a focus on the extent to which a patient's
4 pain is relieved, created a practice environment that,
09:10:55 5 although intended to promote pain assessment and
6 effective treatment, in general ultimately led to an
7 increase in opioid prescriptions."

8 Do you see that?

9 A. Yes, sir.

09:11:05 10 Q. And then it continues, "Despite the substantial
11 burden of persistent pain in the United States, access to
12 multi-disciplinary care and reimbursement for
13 nonpharmacologic approaches is woefully inadequate."

14 Can you tell me what that sentence means?

09:11:24 15 A. Yes, sir. Before someone is prescribed an opioid,
16 because of how significant that medication is and how
17 dangerous that is, patients are put through a whole
18 regimen of other nonpharmacological, which means nondrug,
19 therapies.

09:11:39 20 First thing would be to send the patient to
21 physical therapy if they had back pain, to use some of
22 those common over-the-counter products, Ibuprofen,
23 Tylenol, and when those products didn't work, when the
24 prescribers exhausted all those different options and
09:11:56 25 only then are opioids used as a last resource.

1 What this statement is saying,
2 unfortunately, is that some of those alternate therapies,
3 there may not be insurance coverage or funding for those,
4 and patients may not have access to those services.

09:12:09 5 Q. So what the prescribers were telling you is that we
6 might want to put one of our pain patients in physical
7 therapy or some alternative treatment, but because of
8 insurance we're forced to put them on opioid therapy.

9 Right?

09:12:23 10 A. That was their perspective on it, sir, yes.

11 Q. Okay. And what the prescribers told you is that
12 all of these factors that you and I have just discussed
13 have contributed to the routine use of opioid analgesics,
14 right?

09:12:37 15 A. Yes. Again, from the doctors' perspective that's
16 what they felt, sir.

17 Q. Okay. If we can flip now to Page 9, this is a
18 section you can see on the bottom, if I just blow it up,
19 let's do this, let me show you a little bit more.

09:13:05 20 So just to be clear, this is a section that
21 is talking about the pharmacist's responsibilities when
22 it comes to dispensing medications and specifically when
23 it comes to dispensing opioid medications, right?

24 A. Yes, sir.

09:13:21 25 Q. Okay. And if you look at the -- at the last bullet

1 there, right above, it says, "The presentation of
2 controlled substance prescription adds the following
3 complicating factors to the dispensing responsibilities."

4 Do you see that?

09:13:35 5 A. Yes, sir.

6 Q. Okay. And the first bullet point that's listed
7 there is recognizing red flag warnings, right?

8 A. Yes, sir.

9 Q. And that's something that we've talked a bit about
09:13:49 10 on Friday and we'll talk a bit more about today, but that
11 paragraph sort of spells out the responsibilities that
12 the stakeholders had identified when it comes to red
13 flags and dispensing, right?

14 A. No, sir.

09:14:03 15 This was written by the pharmacists, the
16 pharmacy organization, so it would have been Walgreen's,
17 the American Pharmacy Association, and this was one of
18 the primary interactive components between prescribers
19 and others. Not all the responsibilities of the
09:14:19 20 pharmacist was listed in this paragraph, sir, in regard
21 to red flags.

22 Q. I didn't say everything, all the responsibilities
23 were listed in that paragraph.

24 What I said is that paragraph talks about
09:14:29 25 the red flags we've been discussing and what the

1 pharmacist's responsibilities are when it comes to red
2 flags, right?

3 A. Not all the responsibilities, sir.

4 Q. Okay. Well, let's move on.

09:14:39 5 Will you agree with me that that does
6 discuss red flags and what the pharmacists had told the
7 NABP and the DEA the responsibilities were when it comes
8 to red flags?

9 A. One of the responsibilities, recognizing red flags,
09:14:53 10 sir.

11 Q. Okay. Let's then, if we could, please, sir, flip
12 to the following page, and that list then continues, and
13 I'll just blow that up.

14 I'm having trouble with that today.

09:15:08 15 Okay. Another one of the responsibilities
16 that the pharmacists had identified in this document that
17 NABP put out and the DEA worked on is satisfactorily
18 determining legitimacy of the prescription, right?

19 A. Yes, sir.

09:15:25 20 Q. And then it walks through some of the steps that
21 can be taken to determine the legitimacy of the
22 prescription, right?

23 A. Yes, sir.

24 Q. The next bullet then continues, "Accessing PMP
09:15:38 25 data."

1 Do you see that?

2 A. Yes, sir.

3 Q. And we talked about PMP data last week, but
4 that's -- that's the database that a pharmacist can go
09:15:45 5 into and see what other prescriptions the patient may
6 have filled at any pharmacy, right?

7 A. Yes, sir.

8 Q. All right. And then the final bullet point that's
9 listed under the responsibilities for pharmacists in
09:16:02 10 dispensing opioid medication is, "Distribution
11 restrictions implemented by wholesale distributors."

12 Right?

13 A. Yes, sir.

14 Q. Okay. So the document that the DEA participated in
09:16:14 15 creating and that you as the CEO of the NABP supported in
16 final form says nothing about documenting the resolution
17 of red flags in this section on pharmacists'
18 responsibilities, true?

19 A. The specific phrase is not used, sir.

09:16:35 20 Q. Right. I mean, nowhere does it say the pharmacist
21 has an obligation to document the resolution of red
22 flags, right?

23 A. Not in this section, sir.

24 Q. Well, not anywhere in the document, right?

09:16:46 25 A. No, sir.

1 Q. No, sir, I'm incorrect?

2 A. Yes, sir, you're incorrect, sir.

3 Q. Okay. Well, if you can point me to where it is in
4 this document that it states that a pharmacist has an
09:16:59 5 obligation to document the resolution of red flags, I'm
6 all ears.

7 A. Sure.

8 Q. Okay.

9 A. Several times in the document, but I'll give you
09:17:09 10 one reference, if you can turn to Page 13, sir.

11 Q. Okay. Give me one second.

12 A. So the paragraph beginning "When presented," so
13 what it says there --

14 Q. Let me blow it up so everyone can see it, okay?

09:17:29 15 A. So the key points that we talked about on Friday,
16 pharmacists must exercise their professional judgment and
17 must adhere to corresponding responsibility.

18 The document also does not include the word
19 "Diagnosis." Doesn't include the word "Physical -- the
09:17:48 20 words "Physical examination" which pertain to

21 prescribers, and it doesn't specifically say "Document"
22 because the intention of the document was not to outline
23 all the responsibilities the prescribers and pharmacists
24 must engage with that are part of their professional
09:18:03 25 judgment, corresponding responsibility.

1 So words like "Document" and what the
2 pharmacist needs to do to document are assumed to be
3 included in these responsibilities and not something that
4 other practitioners/prescribers should say the
09:18:20 5 pharmacists should be doing it.

6 That was something the pharmacists should
7 know and was defined in those particular terms.

8 Q. Sir, you just asked me to blow up this paragraph,
9 and I want you to show me in this paragraph where it says
09:18:32 10 the pharmacist has an obligation to document the
11 resolution of red flags.

12 A. Yes, sir.

13 As I mentioned, the specific word
14 "Document" is not there, but clearly how pharmacists
09:18:39 15 interpret and how others interpret professional
16 responsibility and corresponding responsibility contains
17 the requirements to document.

18 Q. Well, you said the DEA participated in the creation
19 of this document, right?

09:18:50 20 A. Yes, sir.

21 Q. And the DEA didn't come out and say, "Hey, wait a
22 second, guys, this is missing the most important part,
23 documentation of red flags."

24 The DEA didn't say that, did they?

09:19:02 25 A. As I explained, everyone realized who was at that

1 meeting the corresponding responsibility including
2 documentation.

3 Q. But respectfully, sir, you don't have any idea what
4 everybody understood or realized who participated in that
09:19:15 5 meeting, do you?

6 A. I do, sir, because I participated in the
7 discussions.

8 I was physically at that -- every meeting,
9 and that came up at the meetings, talking about the
09:19:24 10 importance of documentation, and people said from the
11 various groups that that was part of corresponding
12 responsibility, sir.

13 Q. So at this meeting you're saying you talked about
14 how important it was to document the resolution of red
09:19:36 15 flags, and nobody saw fit to put any of that language in
16 this document that you supported in its final form.

17 Is that your testimony?

18 A. Yes, sir.

19 Q. Okay. Let's turn then if we can to the section on
09:19:46 20 red flags, and that's on Page 10.

21 Okay. And do you see there there's a
22 Section 3 which reads, "Factors more indicative of
23 substance abuse or diversion (red flags)"?

24 A. On Page 10? I'm sorry.

09:20:13 25 Q. Well, I thought it was -- yes, Page 10 in the upper

1 right-hand corner.

2 A. Oh, yes.

3 Q. Do you see that?

4 A. Yes, sir.

09:20:22 5 Q. And do you see there the section, Section 3, where
6 it talks about red flags?

7 A. Yes, sir.

8 Q. Okay. And then it talks about red flags for
9 prescribers and then there's a section on red flags for
09:20:36 10 pharmacists who are presented with the prescription,
11 right?

12 A. I talk -- are you referring to Page 13, sir?

13 Q. Yes, sir, I am.

14 A. Okay.

09:20:45 15 Q. Okay. So --

16 A. Do you want me to look at, I'm sorry, 10 or 13 now,
17 sir?

18 Q. I just want to orient everybody that we're in the
19 red flag section now, and then on Page 13 it talks about
09:20:54 20 the red flags for pharmacists, right?

21 A. Yes, sir. Some of the red flags.

22 Q. Okay. And I don't want to go through all of
23 the -- all of the red flags that are listed in this
24 document, but is it safe to say that some of those red
09:21:08 25 flags are included in the red flags that you came up with

1 for this litigation and others are not?

2 A. Yes, sir.

3 Q. I do want to ask you about one of the red flags in
4 here, just very briefly.

09:21:21 5 If you'd turn to Page 14, there's a section
6 on "Medication taking/supply."

7 Do you see that?

8 A. Yes, sir.

9 Q. Okay. And one of those, you can see the second
09:21:41 10 bullet point, "Therapeutic duplication of two or more
11 long-acting and/or two or more short-acting opiates."

12 Right?

13 A. Yes, sir.

14 Q. That's also a red flag that you've come up with in
09:21:55 15 this litigation as one of your 16, right?

16 A. Yes, sir.

17 Q. Can you tell me what are some examples of a
18 long-acting opiate?

19 A. There's various designations that the
09:22:09 20 pharmaceutical companies may use, extended relief,
21 extended sustained relief, so some of the opioid products
22 like OxyContin, ES or such have an extended release which
23 would be a long-term acting opiate, sir.

24 Q. And what about what are some of the examples of
09:22:27 25 short-acting opiates?

1 A. Short would be just an OxyContin 30 milligram,
2 OxyContin 80 milligram, Hydrocodone, whatever strength,
3 the 325, 10 milligram, those that don't have the extended
4 release or sustained release or long-acting designations
09:22:43 5 after them.

6 Q. One opioid I've heard talked about is Methadone.

7 Is that a long acting or short acting?

8 A. That's a rather complicated question, sir, to
9 answer because Methadone just recently was approved for
09:22:59 10 pain management, and it is very difficult to dose
11 Methadone because of how quickly it is absorbed into the
12 body and how long it stays in the body.

13 So some people may consider it long acting,
14 short acting. It's not supposed to be used in pain
09:23:14 15 management unless that person's very specifically
16 trained, and the patient is very carefully monitored.

17 As many of you know, it's used as an
18 alternative to heroin, so people that don't utilize
19 heroin, they use Methadone, but from a clinical
09:23:29 20 perspective, sir, it's difficult for me to answer that
21 question.

22 Q. Okay. So it could be long acting, it could be
23 short acting, depending how it's --

24 A. Depending how the patient reacts to it, sir.

09:23:38 25 Q. Okay. If we could flip, please, sir, a couple of

1 pages to Page 15. So the document here lists all the red
2 flags, and then -- oh, I went one past it.

3 Do you see there there's a Section 4?

4 A. Yes, sir.

09:23:59 5 Q. And it reads, "Other aberrant medication-related
6 behaviors and factors potentially indicative of substance
7 abuse or diversion."

8 Right?

9 A. Yes, sir.

09:24:12 10 Q. Okay. And this apparently is a pretty literate
11 group.

12 Aberrant, that means abnormal?

13 A. No, sir. That's behavior outside of the normal.

14 Q. So abnormal?

09:24:22 15 A. Yes, sir.

16 Q. Okay. So if you could flip then -- so this is the
17 section then that's talking about other abnormal
18 behaviors that may potentially be indicative of
19 diversion, right?

09:24:40 20 A. Yes, sir.

21 Q. And if you flip then just one page, and I'll blow
22 it up for you, these two paragraphs, it talks about
23 abnormal behaviors that a pharmacist should be on the
24 lookout for, right?

09:24:53 25 A. Yes, sir.

1 Q. Okay. And it says, let me just highlight here, it
2 says, "While the above factors," and that was like the
3 long acting, short acting factors, "or red flags are more
4 indicative of substance abuse or diversion, oftentimes
09:25:20 5 more subtle aberrant or abnormal behaviors exist, that
6 while in and of themselves may not be problematic, may
7 indicate a potential issue that warrants further
8 evaluation prior to dispensing."

9 Right?

09:25:33 10 A. Yes, sir.

11 Q. And then it continues, and let me just get it
12 highlighted, then we can read it together, "Aberrant
13 behaviors that patients may exhibit upon the presentation
14 of the prescription include traveling unexplainable
09:25:54 15 and/or unreasonably long distance to a physician office
16 and/or the pharmacy or requesting to pay cash for a
17 controlled substance prescription, when it has been
18 documented that he or she has insurance that would
19 normally cover the prescription."

09:26:10 20 Right?

21 A. Yes, sir.

22 Q. I want to pause on each of those for just a moment.

23 The first non-red flag, abnormal behavior,
24 is traveling an unexplainable and/or unreasonably long
09:26:27 25 distance to the doctor or pharmacy, right?

1 A. If I may, sir, I think you said non-red flag.

2 These are additional red flags, not non-red
3 flags, sir.

4 Q. We'll talk about that.

09:26:38 5 Do you see this issue, though, of somebody
6 traveling an unreasonably long distance to the pharmacy?

7 A. Yes, sir.

8 Q. And I think that's something that you put into your
9 red flag bucket in this, in the red flags you came up
09:26:56 10 with for this lawsuit, right?

11 A. Yes, sir.

12 Q. You testified last week that a patient with the
13 prescription might elect to visit the pharmacy close to
14 where that person works because that's more convenient
09:27:10 15 than getting the prescription filled closer to the
16 person's home, right?

17 A. That's what studies have shown, and I testified to,
18 sir, yes.

19 Q. Yeah. And you agree that's pretty common, right?

09:27:20 20 A. Yes, sir.

21 Q. Your analysis, the red flag analysis you talked
22 about on Thursday or Friday, that's based on the distance
23 between where the patient lives and where the pharmacy
24 is, right?

09:27:34 25 A. There were two red flags.

1 One where the patient lived and the
2 pharmacy was located, and one where the patient lived and
3 the prescriber was located, sir.

09:27:46

4 Q. Yeah, I understand. I'm focusing on the pharmacy
5 now, okay?

6 A. Yes, sir.

7 Q. So your analysis, when it comes to the pharmacy, is
8 based on the distance from where the patient lives to
9 where the pharmacy is located, right?

09:27:58

10 A. Yes, sir.

11 Q. And you don't have any idea where any of those
12 folks who are filling their prescriptions, you don't have
13 any idea where they work, you just know where they live,
14 right?

09:28:08

15 A. Right.

16 We talked -- I talked about with the jury
17 last week that that would be an exception if a person had
18 the prescription filled where they work or there was some
19 other reason that could be explained and the red flag
20 resolved, sir.

09:28:18

21 Q. Right. But when you are doing your analysis, you
22 don't have any idea how many of the folks that you have
23 flagged were filling prescriptions close to where they
24 work rather than close to where they lived, right?

09:28:30

25 A. Correct, sir.

1 Q. Okay. The second aberrant behavior indicated here
2 says, "When a patient requests to pay cash when it's been
3 documented that he or she has insurance that would
4 normally cover the prescription," right?

09:28:45

5 A. Yes, sir.

6 Q. Why does it matter if the patient has insurance?

7 A. The -- well, if you're filling a prescription at a
8 pharmacy and you would submit it to insurance, that claim
9 is reviewed by your insurance company.

09:29:00

10 And the insurance companies then review the
11 clinical requirements of that prescription as well as
12 whether or not that prescription should be reimbursed
13 for, and one of the biggest issues that pharmacies
14 struggle with is insurance companies rejecting claims or
15 clawing back payment from pharmacies.

09:29:15

16 So if you submit something to insurance, it
17 has to be perfect. Otherwise, the pharmacy's not going
18 to get paid for it and that creates a significant
19 problem.

09:29:27

20 People utilize cash, then, to avoid that
21 second or third review by an insurance company that the
22 pharmacy may not do or that the pharmacy may miss.

23 Q. So when you were doing your red flag analysis, did
24 you include that limitation that they're paying cash but
09:29:44 25 they have insurance?

1 A. I -- the red flag, I'm not sure how Dr. McCann
2 pulled those, but my direction to Dr. McCann was if any
3 of the patients paid with cash or a discount card or
4 anything indicated outside of insurance that that should
09:30:02 5 be flagged, sir.

6 Beyond that, I'm not sure what else was
7 pulled.

8 Q. So it could have been that the folks that you
9 flagged in your analysis, they paid with cash because
09:30:09 10 they didn't have insurance and you just don't know that,
11 correct?

12 A. Correct, sir. That was one of the exceptions we
13 spoke about last week as well.

14 Q. And I think you said last week that the industry
09:30:18 15 standards and information from the industry show that 90
16 to 95 percent of all patients have some sort of insurance
17 coverage for their medications, right?

18 A. Yes, sir.

19 Q. And what that means is there is 5 to 10 percent of
09:30:34 20 the population out there that doesn't have some sort of
21 insurance, right?

22 A. Yes, sir.

23 Q. The only option for those folks is to pay cash or
24 not get health coverage?

09:30:43 25 A. Correct.

1 Q. Health care, right?

2 A. Correct. That's why the notes are so critical to
3 document that, and I didn't see any documentation in the
4 notes that indicated like that saying patient does not
09:30:53 5 have insurance, must pay cash, sir.

6 Q. But given your data you would expect that 5 to 10
7 percent of the folks who present a script at any of the
8 pharmacies don't have insurance just based on the data,
9 right?

09:31:04 10 A. Right. Not being an expert that would make sense,
11 that if there's a percentage of people that don't have
12 insurance, there's probably that same percentage that
13 would be reflected in the prescriptions as well.

14 Q. If we could flip, and I'm almost done with this
09:31:22 15 document, to Page 17, the next page, and what we were
16 just talking about there is what the stakeholders had
17 called other aberrant behaviors, right?

18 A. Yes, sir.

19 Q. And what the document that your organization put
09:31:41 20 out, you supported, said is that "Whereas these abnormal
21 behaviors we've just been talking about may be indicative
22 of potential drug abuse and/or diversion, they are not in
23 and of themselves positive identifiers that unequivocally
24 result in a pharmacist taking specific actions or be used
09:32:03 25 to establish general standards of care or to inform

1 statutory or regulatory requirements."

2 Right?

3 A. Yes, sir.

09:32:15

4 Q. In the red flags you came up for for this
5 litigation, you say that distance and cash is a red flag
6 that unequivocally means a pharmacist has to take action,
7 right?

8 A. Yes, sir.

09:32:26

9 Q. And the stakeholders document that you participated
10 in creating, that DEA participated in creating, in
11 its -- those conditions don't make the test of red flags,
12 do they?

09:32:42

13 A. The next sentence, sir, if you could read that, it
14 says, "These types of behavior should, however, result in
15 an increased vigilance with taking all patient
16 circumstances into consideration."

09:32:56

17 What I testified is that the pharmacist
18 must identify red flags and then resolve those red flags,
19 and if the red flags are resolved, then the pharmacist is
20 safe to dispense the prescription, sir.

09:33:14

21 Q. And you would agree with me that the red flags and
22 other abnormal behaviors that you created for the
23 plaintiffs' lawyers in this litigation are different from
24 the red flags and behaviors that went into the document
25 that you blessed as the head of the NABP, right?

1 A. They are not different, sir.

2 The document doesn't include all the red
3 flags, but those other red flags are noted in the
4 footnotes and the various DEA cases. If you turn to the
09:33:28 5 document, there's a number of references that point to
6 the other red flags that are mentioned in my report, sir.

7 Q. And the red flags that you created for this
8 litigation are different than the criteria that the DEA
9 has identified in its *Pharmacist's Manual*, true?

09:33:46 10 A. No, sir, because the DEA clarified the pharmacy
11 manual by the Court actions it took in the *Holiday*, the
12 *Hills*, the *East Main Street* pharmacies, and so the red
13 flags I identified were identical to what the DEA has
14 said, sir.

09:34:00 15 Q. Well, sir, if the red flags that you created for
16 this litigation were the law --

17 MR. LANIER: Your Honor, objection to form.
18 At some point I have to object.

19 He keeps saying the red flags that you
09:34:13 20 created for this litigation.

21 This witness didn't create these red flags
22 for this litigation. And to put that into the
23 question --

24 THE COURT: Okay. I'll sustain the
09:34:21 25 objection the way the question was asked.

1 MR. LANIER: Thank you.

2 BY MR. SWANSON:

3 Q. The red flags that you have testified
4 about -- well, the red flags you've testified about in
09:34:28 5 this litigation were red flags that you identified and
6 you gave them to Dr. McCann, right?

7 A. There were red flags that the DEA and cases
8 identified, and then I presented those identified red
9 flags to Dr. McCann, sir.

09:34:41 10 Q. Well, sir, if the red flags that you have been
11 talking about in this litigation were the law or the
12 standard practice for pharmacists, there wouldn't be any
13 need to get this stakeholder group together to develop a
14 set of red flags, true?

09:34:57 15 A. Well, sir, at the beginning when you first started
16 talking about this, the primary purpose was to open up
17 lines of communication between the doctors and
18 pharmacists because those lines of communication had
19 broken down, and the purpose of this document and
09:35:11 20 identifying some of the red flags was reaching a common
21 ground between the pharmacists and the doctors on what
22 each other's responsibilities were.

23 It wasn't to say these are the definitive
24 list of red flags that everyone must follow and here's
09:35:23 25 what everyone must do, sir.

1 Q. Let me conclude on this issue of red flags with a
2 couple specific things you talked about last week.

3 The first one is you said, I think, and you
4 can correct me if I get it wrong, but I think you said
09:35:45 5 that all of the 16 red flags that you have been using in
6 this litigation, all of them can be resolved except one,
7 right?

8 A. Yes, sir.

9 Q. And the one that you said can't be resolved is what
09:35:57 10 you've called a trinity prescription, right?

11 A. Yes, sir, the opioid, the Benzodiazepine, the Xanax
12 and such --

13 THE COURT: Mr. Catizone.

14 THE WITNESS: I'm sorry.

09:36:10 15 THE COURT: Particularly when you're giving
16 drug terms or long words, I need you to slow down.

17 Thanks.

18 A. The trinity again is a combination of three drugs,
19 and there are several trinities, but the one specifically
09:36:23 20 in this example is an opioid, and there is a

21 Benzodiazepine, which we've talked about could be Xanax,
22 Valium, and then the third is a muscle relaxant, and it's
23 Carisoprodol, C-A-R-I-S-O-P-R-O-D-O-L, brand name
24 generally Soma.

09:36:45 25 That's the trinity, sir, that I was

1 referring to.

2 Q. And in your opinion, as you've testified in this
3 case, if that prescription is presented, that red flag
4 can never be resolved, right?

09:36:54 5 A. The resolution, sir, is to not dispense that
6 prescription.

7 Q. Okay. So a physician or prescriber should never
8 write a trinity prescription according to you, right?

9 A. Yes, sir.

09:37:06 10 Q. And you understand that your position, you've just
11 articulated, is inconsistent with the position of the DEA
12 on this issue, right?

13 A. I'm not familiar what the position of the DEA is on
14 this issue, sir.

09:37:20 15 Q. So you didn't know that the DEA's position is that
16 it's up to the prescriber to make determinations as to
17 what to prescribe?

18 A. I based my response upon the fact that when we met
19 with the stakeholder group and there were pain management
09:37:33 20 physicians there and family practitioners and other
21 practitioners, the prescribers in that group all
22 agreed --

23 MR. SWANSON: Your Honor, I have to object
24 to this hearsay.

09:37:42 25 THE COURT: Well, it's not hearsay.

1 MR. SWANSON: What's that?

2 THE COURT: He answered. This is his
3 answer, I mean, but this is his answer, so overruled.

4 A. During that stakeholder meeting, those prescribers
09:37:56 5 who are experts outside of me as a pharmacist said there
6 was no legitimate medical purpose to prescribe those
7 three drugs together.

8 BY MR. SWANSON:

9 Q. So, sir, what I want to do is I want to go back to
09:38:07 10 the DEA's position that he had asked you about.

11 And I've put up on the screen here a letter
12 you can see dated July 12th, 2019, from three different
13 organizations.

14 Do you see at the top there NACDS?

09:38:28 15 A. Yes, sir.

16 Q. And I think you spoke about them last week, that's
17 the National Association of Chain Drug Stores?

18 A. Yes, sir.

19 Q. And then from the American Pharmacists Association,
09:38:40 20 do you see that?

21 A. Yes, sir.

22 Q. And what is that organization?

23 A. It's very similar to the American Medical
24 Association. It's an individual organization -- it's an
09:38:49 25 organization for individual pharmacists.

1 Q. And then the last is the NCPA, National Community
2 Pharmacists Association, what is that?

3 A. That's a subgroup within pharmacy. It's all of the
4 pharmacists who own pharmacies rather than the individual
09:39:07 5 pharmacists who may be employees of chains or other
6 employers.

7 Q. Okay. And just so it's a little easier to see I'm
8 going to blow it up. So those three entities are sending
9 a letter, and I might not have made it clear, you can see
09:39:24 10 the letter they are putting out has gone to the DEA.

11 Do you see the two addressees up there?

12 A. Yes, sir.

13 Q. Okay. So now let me see if I can blow it up so
14 folks can read it.

09:39:42 15 So they are following up on a discussion
16 that they had had with the DOJ and it says, "We seek
17 written clarification with respect to a central
18 allegation in the U.S. complaint."

19 Do you see that?

09:39:56 20 A. Yes, sir.

21 Q. And then the allegation is that there's no medical
22 basis for the simultaneous prescription of any version of
23 the three trinity drugs, do you see that?

24 A. Yes, sir.

09:40:06 25 Q. And that's the trinity drugs that you've just been

1 talking about?

2 A. Yes, sir.

3 Q. And they say, "Insofar as we are aware, neither DOJ
4 nor DEA has otherwise asserted that there can never be a
09:40:27 5 medical basis to prescribe the trinity drugs. The CDC
6 has stated that clinicians should avoid prescribing
7 opioids and Benzodiazepines concurrently whenever
8 possible."

9 Right?

09:40:39 10 A. Yes, sir.

11 Q. And then if you just look over to the next page,
12 they say, they conclude this letter, "To clear any
13 confusion, we ask that you provide guidance in writing
14 that neither DOJ nor DEA have a position on the medical
09:41:02 15 basis to prescribe specifically the simultaneous of any
16 version of the three trinity drugs, or generally any
17 prescription drug therapy."

18 Right?

19 A. Yes, sir.

09:41:14 20 Q. And then it's signed by those three organizations,
21 do you see that?

22 A. Yes, sir.

23 Q. And I see that the representative of the APA is
24 Thomas Menighan.

09:41:24 25 Could you remind us who that is?

1 A. Sure, the Thomas Menighan who is listed here is the
2 CEO of the American Pharmacies Association. He is
3 currently one of my two partners in my consulting
4 business.

09:41:36 5 Q. Okay. So he's signing off on a letter to the DEA
6 saying we seek guidance on whether it's appropriate for
7 doctors ever to prescribe the trinity, right?

8 A. Yes, sir.

9 Q. Okay. I want to put up now the response from the
09:41:56 10 DEA.

11 So do you see here I've put up a November
12 4th, 2019 letter to Mr. Nicholson?

13 A. Yes, sir.

14 Q. And he was one of the authors of that letter we
09:42:08 15 just looked at, right?

16 A. Yes, sir.

17 Q. And what I'm going to do here is try to get both
18 pages of the letter so that we can see it.

19 Okay. And let me just blow up the
09:42:27 20 conclusion so everyone has it.

21 I don't want to highlight it, I want to
22 blow it up.

23 Okay. So do you see that the response from
24 the DEA is that, "The DEA has not promulgated new
09:43:02 25 regulations regarding the treatment of pain. Federal law

1 and DEA regulations do not impose a specific quantitative
2 minimum or maximum limit on the amount of medication that
3 may be prescribed on a single prescription, or the
4 duration of treatment intended with the prescribed
09:43:20 5 controlled substances. The DEA has consistently
6 emphasized and supported the prescriptive authority of an
7 individual practitioner under the CSA to administer,
8 dispense, and prescribe controlled substances for the
9 legitimate treatment of pain within acceptable medical
09:43:38 10 standards."

11 That was the position of the DEA, right?

12 A. In regard to the Controlled Substances Act, sir.

13 Q. Right. In regard to the holy trinity prescription,
14 right?

09:43:50 15 A. No, sir.

16 Q. Sir. This letter is responding to a specific
17 request for clarity regarding prescribing trinity drugs,
18 right?

19 A. Yes, sir.

09:44:02 20 Q. And the DEA is saying we leave that position up to
21 the prescriber, right?

22 A. No, sir.

23 Q. The DEA is saying that federal law and DEA
24 regulations do not impose a specific quantitative minimum
09:44:20 25 or maximum limit on the amount of medication that may be

1 prescribed or the duration of treatment, right?

2 A. But it's not answering the question in the letter,
3 sir.

4 If we could go to your first page.

09:44:31 5 Q. Sure.

6 A. And if you could highlight an important section,
7 please.

8 Q. I'm sorry?

9 A. If you could highlight an important section, that
09:44:39 10 second paragraph, please.

11 So what this says is that the DEA cannot
12 provide information outside of the Controlled Substances
13 Act and what those regulations mean.

14 It's been longstanding policy not to
09:45:01 15 provide legal advice to private parties. All federal
16 agencies, including the DEA, can only opine or opinion or
17 talk about what the law says and what the law is.

18 The question specifically asked in the
19 previous letter, can we prescribe or is it okay to
09:45:16 20 prescribe the trinity, the DEA never said, "Yes, you can
21 prescribe the trinity, or no." It simply said we can
22 only comment on what the Controlled Substances Act says,
23 here's what it says, and you make individual decisions in
24 what you prescribe based upon what the law says.

09:45:35 25 We can't tell doctors what to do or not to

1 do in terms of those patient decisions because that's
2 left to the State Medical Boards.

3 The DEA only can enforce the Controlled
4 Substances Act and there's nothing in there saying what
09:45:49 5 prescribers have to do with their patients or should do
6 with their patients to prescribe, sir.

7 Q. I want to move to another statement you said last
8 week.

9 You said, I think it was in response to
09:46:01 10 Mr. Lanier's questions, that as a pharmacist, you get to
11 know the patients who frequent your pharmacy, you know
12 the prescribers in the area, so you're familiar with
13 those prescribers.

14 Do you remember giving that testimony?

09:46:13 15 A. Yes, sir.

16 Q. And I guess, and that's probably especially true in
17 the smaller towns and communities like some of the rural
18 areas around Trumbull County?

19 A. I think it's true for most pharmacies, but
09:46:28 20 probably, yes, sir, in smaller towns, they probably know,
21 have a smaller patient population, sir, yes.

22 Q. Okay. But it's not limited to smaller towns.

23 Any pharmacist tends to know the patients
24 who come in regularly and the prescribers who prescribe
09:46:42 25 regularly, right?

1 A. Yes, sir.

2 Q. We'll start with patients.

3 You agree with, I think you just said, but
4 pharmacists frequently create relationships with the
09:46:49 5 patients who come in to see them, right?

6 A. Yes, sir.

7 Q. And through those relationships, the pharmacists
8 can learn the patient's medical condition, right?

9 A. Yes, sir.

09:46:58 10 Q. And can learn the patient's treatment plans, right?

11 A. Yes, sir.

12 Q. And that includes whether the patient's being
13 treated for a chronic condition like rheumatoid
14 arthritis, right?

09:47:09 15 A. Yes, sir.

16 Q. And they might know the treatment plan that that
17 patient is getting for rheumatoid arthritis, right?

18 A. Yes, sir.

19 Q. And the pharmacists also get to know the
09:47:19 20 prescribers in their community.

21 True?

22 A. Yes, sir.

23 Q. So a pharmacist, for example, might know that two
24 doctors in town are part of the same practice, right?

09:47:29 25 A. Yes, sir.

1 Q. So if they're getting prescriptions from that
2 practice, even though it's from two different doctors,
3 that's something that the pharmacist might understand
4 because he has a relationship with those physicians,
09:47:40 5 right?

6 A. Yes, sir.

7 Q. And you agree that's common, right?

8 A. Yes, sir.

9 Q. And do you agree with me that no -- that a
09:47:50 10 pharmacist, knowing the patients and knowing the
11 prescribers in the community, that can help to resolve
12 red flags or resolve situations that might otherwise be a
13 red flag, right?

14 A. As long as the pharmacist documents that, sir, yes.

09:48:07 15 Q. Well, we'll get to that.

16 But my first question is that might help
17 the pharmacist understand why a prescription is being
18 provided that might otherwise be a red flag if the
19 pharmacist didn't know the patient and the doctor, right?

09:48:20 20 A. Yes, sir.

21 Q. So if a pharmacist knows that a patient is
22 suffering from rheumatoid arthritis, is on opioid therapy
23 from a doctor that the pharmacist also knows, that
24 prescription might not be a red flag to that pharmacist,
09:48:35 25 right?

1 A. May not be to that pharmacist, but to other
2 pharmacists, sir.

3 Q. So, okay, so but at least for the pharmacist who is
4 dispensing to that patient, he or she can take in that
09:48:49 5 prescription, saying Ms. Smith, I hope you're feeling
6 better, here's your prescription, right?

7 A. Correct, as again the documentation is critical.

8 Q. But you're not saying that every time a patient
9 with rheumatoid arthritis comes into the pharmacy, a
09:49:07 10 pharmacist has to sit down and say Ms. Smith has
11 rheumatoid arthritis, she's been taking this opioid
12 therapy for two years, it's okay to fill, I'm going to
13 call the doctor.

14 They don't have to take all of those steps
09:49:18 15 every time for a patient that the pharmacist knows, do
16 they?

17 A. Anytime there's an opioid involved and there are
18 red flags involved, the answer is yes, sir.

19 Q. Okay. Sir, you testified on direct that you
09:49:29 20 haven't filled a prescription as a pharmacist since
21 probably around 2000, right?

22 A. Yes, sir.

23 Q. So it's been 20 years or so since you stood behind
24 the counter, evaluated a prescription, and had to make a
09:49:44 25 sometimes difficult decision about whether or not to

1 dispense that medication, right?

2 A. Yes, sir.

3 Q. In arriving at your opinions in this case, you
4 didn't talk to any current pharmacists at any of the
09:49:57 5 chain pharmacies like Walgreen's, right?

6 A. I don't think that would be appropriate, sir, but
7 no, I did not.

8 Q. Well, I'm not limiting it to Walgreen's.

9 You didn't go out to any chain pharmacy,
09:50:08 10 any currently practicing pharmacist, and talk to them
11 about the current conditions in Ohio, right?

12 A. No, sir.

13 Q. And you didn't visit any Walgreen's pharmacies in
14 Lake or Trumbull County, right?

09:50:19 15 A. No, sir.

16 Q. Have you ever been to Lake or Trumbull County?

17 A. Probably so. My daughter went to Miami of Ohio,
18 and I'm sure I've probably driven around trying to find
19 out where she was on a Saturday night, but otherwise I'm
09:50:30 20 not sure, sir.

21 Q. Do you know what cities or towns in Lake or
22 Trumbull County have a Walgreen's pharmacy?

23 A. When I was preparing my report I did look at how
24 many pharmacies Walgreen's, Walmart, CVS were in those
09:50:46 25 counties, but I don't have that information readily

1 available, sir.

2 Q. Do you know the largest pharmacy by volume in
3 Trumbull County?

4 A. No, sir.

09:50:55 5 Q. The jury has heard about a pharmacy in Trumbull
6 County called Overholt's Pharmacy.

7 Have you ever heard of Overholt's?

8 A. No, sir.

9 Q. They've heard about another pharmacy in Trumbull
09:51:07 10 County called Franklin Pharmacy.

11 Have you ever heard of them?

12 A. No, sir.

13 Q. You didn't speak to any doctors in Lake or Trumbull
14 County about the prescribing practices in those counties
09:51:14 15 in arriving at your opinions, right?

16 A. No, sir.

17 Q. You didn't investigate what the medical standard of
18 care was in those counties in arriving at your opinions,
19 right?

09:51:22 20 A. I base my opinion on what the medical standard of
21 care was in regard to the Controlled Substances Act,
22 which is the same in Lake and Trumbull County as it would
23 be across the country, sir.

24 Q. Okay. So you know, then, that there was an
09:51:32 25 increase in prescribing opioids over time in the period

1 you looked at, right?

2 A. Yes, sir.

3 Q. And you understand that prescribers exercise their
4 own professional judgment in deciding whether to
09:51:43 5 prescribe an opioid medication, right?

6 A. Yes, sir.

7 Q. All right. I want to flip now to talk about
8 Walgreen's a little bit more specifically, okay?

9 A. Yes, sir.

09:51:53 10 Q. One of the things that you did on your direct with
11 Mr. Lanier is you talked about a set of prescriptions
12 from Walgreen's that you had reviewed.

13 Do you recall that?

14 A. Yes, sir.

09:52:05 15 Q. And I believe the number was 2,000 prescriptions?

16 A. Approximately, sir, yes.

17 Q. So you -- you reviewed approximately 2,000
18 individual Walgreen's prescriptions, electronic notes
19 fields associated with those scripts, right?

09:52:23 20 A. Yes, sir.

21 Q. And you previously concluded that every one of
22 those prescriptions was a red flag?

23 A. No, sir.

24 I didn't conclude that. The prescriptions
09:52:33 25 were sorted by Dr. McCann, and every one of the

1 prescriptions that I was presented with had either one or
2 multiple red flags.

3 Q. Okay. So I think we're saying the same thing.

4 That set of 2,000, according to you and Dr.
09:52:46 5 McCann, those were all red flags?

6 A. Yeah. According to Dr. McCann's analysis and my
7 review of it, yes, sir.

8 Q. And then according to you, there were insufficient
9 notes on a number of those scripts that you reviewed,
09:52:59 10 right?

11 A. Yes, sir.

12 Q. Are you familiar, sir, with Intercom Plus?

13 A. Yes, I am.

14 Q. And can you tell us what that is?

09:53:05 15 A. That's Walgreen's computer system, and so
16 Walgreen's utilized Intercom Plus or Intercom for its
17 dispensing. It provided its dispensing system as well as
18 its alerts for various drugs.

19 When Walgreen's was purchased by Boots
09:53:24 20 Pharmaceutical in the UK, there was a move to change
21 Intercom Plus --

22 Q. Dr. Catizone, can I cut you off? I just asked you
23 what it was.

24 A. Yes, sir.

09:53:36 25 MR. LANIER: He asked, "Can you tell us

1 what it is," and that's the answer he was given.

2 THE COURT: I think he finished the answer.

3 If you want to come back on redirect, Mr. Lanier, you
4 may.

09:53:43 5 MR. LANIER: Thank you.

6 BY MR. SWANSON:

7 Q. Now, Mr. Catizone, the jury is going to hear a lot
8 more about Intercom Plus when the Walgreen's folks
9 testify, but I think as you were saying, it's a system so
09:53:52 10 when a prescription comes into Walgreen's, the pharmacist
11 takes the prescription and enters a bunch of data into
12 Intercom Plus, right?

13 A. Correct. Either the pharmacist or the technician,
14 sir.

09:54:02 15 Q. Or both, right?

16 A. Correct, sir.

17 Q. And so the Intercom Plus system, that contains
18 information and data about the patient beyond whatever
19 you're saying with just the prescription that's been
09:54:14 20 presented, right?

21 A. Yes, sir. Information that the pharmacist or
22 technician would collect about the -- collect about the
23 patient, yes, sir.

24 Q. True. But it's also going to have historical
09:54:26 25 information about the patient if the patient has filled a

1 prescription at Walgreen's, right?

2 A. Yes, sir.

3 Q. So if it's a patient who comes in every month with
4 a prescription, when the pharmacist sits down in Intercom
09:54:37 5 Plus, he or she is going to see not just what's in the
6 prescription before her but the information that's been
7 collected from those previous fills, right?

8 A. I believe so, sir, but I don't remember if
9 Walgreen's Intercom Plus had a delete time period where
09:54:52 10 after so much time period then the information would be
11 deleted, but if it didn't have that, then yes, sir.

12 Q. Okay. So if a patient had come in previously to
13 fill a prescription, there would be information about
14 that patient in the system, right?

09:55:06 15 A. Correct, sir.

16 Q. Now, when you looked at those 2,000 prescriptions
17 that you testified about on direct, you only looked at
18 the prescription that was before you and you didn't look
19 at any of that historical data that was in the Intercom
09:55:22 20 Plus system, right?

21 A. Any historical data, sir, that was in the notes,
22 and there was information in the notes about some
23 patients, I looked at that information, sir.

24 Q. Right. But you didn't go back and look at all of
09:55:32 25 the previous fills that those patients in those 2,000

1 scripts that were contained in Intercom Plus, you didn't
2 do that, right?

3 A. I didn't have access to that data, sir.

4 Q. Well, let's talk about that.

09:55:44 5 Did you know or would you be surprised to
6 learn that 97 percent of the patients in those 2,000
7 prescriptions that you reviewed, 97 percent had
8 previously filled a prescription at Walgreen's? Did you
9 know that?

09:56:00 10 A. No, sir.

11 Q. And so the Intercom Plus had data on 97 percent of
12 the patients whose scripts you looked at in those 2,000.

13 Fair?

14 A. Yes, sir.

09:56:15 15 Q. And I take it that the plaintiffs' lawyers didn't
16 tell you that Walgreen's produced all of that data, all
17 of that data on those 97 percent of those patients.

18 You didn't know that, did you, sir?

19 A. All I knew, sir, was the data what was presented to
09:56:32 20 me. I didn't know what was presented or not presented.

21 Q. So you didn't know that Walgreen's had produced
22 more than 150,000 records for the 97 percent of the
23 patients that you evaluated, is that true?

24 A. Again, sir, I don't -- what was reviewed was what
09:56:48 25 was presented to me. I didn't know about any other data

1 set, sir.

2 Q. Well, would you have liked to have known that that
3 other information was available to you when you were
4 coming up with your opinions in this case?

09:56:56 5 A. When I looked at the sample and what information
6 was there for those patients and in those notes, and then
7 what I also found that the good faith dispensing policy
8 that Walgreen's had that required that to be completed
9 for patients that had certain opioids and only one-third
09:57:12 10 of those forms were filled, I'm not sure that anything in
11 those other data would have changed my opinion or
12 indicated otherwise based upon the samples that I looked
13 at, sir.

14 Q. Sir, my question was simply would you have liked to
09:57:25 15 have known that that 150,000 records was available for
16 you to review if you wanted to?

17 Would you have liked to have known that?

18 A. It's a tough question to answer, sir, because I
19 don't know what was in that data set.

09:57:36 20 Clearly if I have more information, more
21 information would be helpful, sir.

22 Q. So, for example, if one of the prescriptions, one
23 of those 2,000 prescriptions that you looked at was for a
24 cancer patient, there may have been a record in the
09:57:51 25 patient's history that said, "This patient is a cancer

1 patient," you wouldn't know that because you didn't look
2 at that history, right?

3 A. The assumption, sir, was that the history would be
4 part of that record that was provided to me to review.

09:58:04 5 If it wasn't provided, then I don't know
6 where else that would have been available to look at,
7 sir.

8 Q. But you were willing to draw conclusions about
9 2,000 prescriptions without looking at all the data that
09:58:18 10 was available to you that Walgreen's had produced.

11 True?

12 A. I drew my opinion based upon that, sir, yes.

13 Q. Now, switch gears a little bit.

14 On direct with Mr. Lanier you discussed two
09:58:30 15 or three specific prescriptions that you looked at that
16 Walgreen's pharmacists had filled that you claim they
17 shouldn't have filled, right?

18 A. I claimed that those red flags weren't resolved and
19 they should have been resolved before being dispensed,
09:58:44 20 sir.

21 Q. So you agree you say those shouldn't have been
22 filled, right?

23 A. Yes.

24 Q. I want to ask you about Walgreen's refusal to fill
09:58:55 25 and policy of refusing to fill.

1 You've seen Walgreen's policies that state
2 explicitly that a pharmacist may always use her
3 professional judgment to refuse to fill a prescription if
4 she believes it doesn't meet the corresponding
09:59:07 5 responsibility, right?

6 A. I believe that's one of the policies, yes, sir.

7 Q. And you know that Walgreen's pharmacists did, in
8 fact, refuse to fill many, many prescriptions that didn't
9 meet Walgreen's policies for dispensing, right?

09:59:20 10 A. I did not see that information in any of the data I
11 reviewed, sir.

12 Q. So when you were giving your opinions, you're
13 telling me that the plaintiffs' lawyers didn't give you
14 the files that Walgreen's produced of its refusals to
09:59:33 15 fill prescriptions?

16 A. When I reviewed the data I specifically looked for
17 refusals to fill or anything in those notes that would
18 have indicated that that prescription was not filled or
19 the pharmacist refused to fill it, and I did not see any
09:59:47 20 data like that, sir.

21 Q. Behind Tab 2, I've put it up on the screen, is a
22 prescription.

23 You recognize that as a prescription,
24 right?

09:59:57 25 A. Yes, sir.

1 Q. From March of 2018, written by a doctor at the
2 Cleveland Clinic, right?

3 A. Yes, sir.

4 Q. And you can see the notes on the bottom from the
10:00:14 5 Walgreen's pharmacist, right?

6 A. Yes, sir.

7 Q. And I'm going to blow up those notes so everyone
8 can see.

9 The pharmacist who got this prescription,
10:00:31 10 Walgreen's pharmacist who got this prescription writes,
11 "Rx turned away."

12 You know that that means that the
13 pharmacist didn't fill that prescription, right?

14 A. Yes, sir.

10:00:41 15 Q. "Called the doctor for diagnosis, treatment plan,
16 and" something unintelligible at least to me, do you see
17 that?

18 A. Yes, sir.

19 Q. "Also, patient gets other prescriptions from Giant
10:00:55 20 Eagle."

21 So also goes to a different pharmacy,
22 right?

23 A. Yes, sir.

24 Q. It says "The doctor's office called back with no
10:01:02 25 further information other than just fill it. So I

1 advised with no information, I wouldn't fill it."

2 Is that what it says?

3 A. Yes, sir.

4 Q. So even though the pharmacist just called the
10:01:15 5 doctor, the doctor didn't satisfy the pharmacist that the
6 prescription should be dispensed, so the Walgreen's
7 pharmacist refused, right?

8 A. That's what the note says, sir, yes.

9 Q. And I assume that you agree that the pharmacist was
10:01:28 10 doing the right thing there, right?

11 A. Yes, sir.

12 Q. And this isn't a document that you've seen or that
13 you were provided with in this litigation?

14 A. I'm sorry, I didn't hear the question, sir.

10:01:37 15 Q. You haven't seen this document before, have you?

16 A. No, sir.

17 Q. If we can look at Tab 4, and by the way, just for
18 the record, these, these are a collection of
19 prescriptions from Plaintiffs' Exhibit P 17230-A.

10:02:06 20 Do you see the document that I put up from
21 behind Tab 4 is a prescription for Roxicodone, right?

22 A. Yes, sir.

23 Q. And here you can see that the Walgreen's pharmacist
24 said that this patient tried to get the prescription
10:02:23 25 early by paying cash, right?

1 A. Yes, sir.

2 Q. And the Walgreen's pharmacist refused to fill that
3 prescription, right?

4 A. Yes, sir.

10:02:30 5 Q. I assume you agree that the pharmacist was doing
6 the right thing in his or her judgment, right?

7 A. Yes, sir.

8 Q. This is another document that the lawyers didn't
9 give you to review in arriving at your opinion, right?

10:02:48 10 A. Correct, sir.

11 Q. Behind Tab 5, another prescription from Walgreen's
12 files, do you see that?

13 A. Yes, sir.

14 Q. And you can see that the first page there is a
10:03:05 15 prescription for Percocet dispense 20, do you see that?

16 A. Yes, sir.

17 Q. And then at the top it says, "Voided, do not fill."
18 Do you see that?

19 A. Just above the words that say "Medical Center"?

10:03:24 20 Q. Yes.

21 A. Yes, sir.

22 Q. And then if you look, what the Walgreen's
23 pharmacist did with this prescription is he or she sent
24 it along to the DEA.

10:03:31 25 Do you see that? Do you see it's a fax to

1 the DEA there?

2 Do you see that?

3 A. I am looking at it now, sir.

4 Q. I'm sorry.

10:03:45 5 A. Yes, sir.

6 Q. So the Walgreen's pharmacist took this prescription
7 and sent it to the DEA with a message.

8 Let's look at that.

9 Okay. So the pharmacist said, "This
10:04:01 10 patient has had seven opioid prescriptions in the last 30
11 days and six in the" whatever "March 10th to April 10th
12 of '14."

13 Right?

14 A. Yes, sir.

10:04:14 15 Q. So this pharmacist has clearly gone into the PDMP
16 database and looked at this patient's prescriptions,
17 right?

18 A. Yes, sir, quite possibly.

19 Q. Or else it was in the Walgreen's system, right?

10:04:24 20 A. Correct.

21 Q. So this pharmacist then called up the doctor that
22 issued the prescription and learned that the doctor had
23 issued that prescription without consulting OARRS.

24 The doctor said he or she was too busy,
10:04:40 25 right?

1 A. Yes, sir.

2 Q. And that the prescription shouldn't have been
3 issued, right?

4 A. Yes, sir.

10:04:45 5 Q. So this is a circumstance where the Walgreen's
6 pharmacist is not only calling the doctor but is telling
7 the doctor you have to check OARRS before you -- before
8 you write these prescriptions, right?

9 A. Yes, sir.

10:04:58 10 Q. He says, "Also this patient had a good faith
11 dispensing refusal and prescription canceled back in
12 2011."

13 Right?

14 A. Yes, sir.

10:05:06 15 Q. So that the Walgreen's system had indicated that
16 this patient had been refused a prescription back in
17 2011, right?

18 A. Yes, sir.

19 Q. Based on all of that information the Walgreen's
10:05:18 20 pharmacist made the decision not to dispense the
21 medication, right?

22 A. Right. It hit all the red flags and what to do
23 with those red flags we discussed, and if they documented
24 this in the patient history so that, as you said, when
10:05:31 25 the Walgreen's pharmacist would look at that patient they

1 would have that information, then, yes, the pharmacist
2 has really practiced as they should.

10:05:43

3 Q. Right. But you don't know one way or the other
4 whether that happened because this isn't a document that
5 you have seen before, correct?

6 A. Correct, sir.

7 Q. Switch gears a little bit, Mr. Catizone.

10:06:01

8 You agree with me that a prescriber can
9 write some prescriptions that don't have a legitimate
10 medical purpose while at the same time writing other
11 prescriptions that do have a legitimate medical purpose,
12 right?

10:06:21

13 A. No, sir. If that prescriber did that they should
14 have their license looked at because I don't know why
15 they would write.

16 Q. I'm just asking you if that can happen. A doctor
17 can write a prescriptions, can write some prescriptions
18 that don't have a legitimate medical purpose and other
19 prescriptions that do have a legitimate medical purpose?

10:06:33

20 A. So I understand, the question is that somebody can
21 break the law and not break the law? Is that the
22 question, that then physicians could then issue a
23 nonlegitimate prescription, violate all the laws and
24 standards, and also issue?

10:06:46

25 The answer would be yes, anyone can break

1 the law or not break the law at different times, sir.

2 Q. So that could occur.

3 Let me ask it a little bit differently.

4 It's not your view that if a prescriber

10:06:58 5 writes one prescription for an opioid medication that

6 doesn't have a legitimate medical purpose then that means

7 that all of the prescriber's opioid prescriptions are

8 invalid and illegitimate, right?

9 A. It would be my position that that physician

10:07:12 10 shouldn't be writing prescriptions because that one

11 prescription could harm or kill that one patient, and,

12 therefore, that prescriber should never issue that

13 prescription.

14 Q. Let me just maybe ask it differently.

10:07:23 15 We've heard a lot about pain clinics in

16 Ohio and elsewhere.

17 You're familiar with pain clinics?

18 A. I think we've referred to them when we've talked

19 about them as pill-mills and pain clinics and different

10:07:36 20 versions.

21 Q. Okay. And is it possible for a doctor at a

22 pill-mill to have a patient who actually needs the

23 medication that that doctor might prescribe?

24 Is that possible?

10:07:47 25 A. It's possible, but again, sir, you're saying if

1 somebody repeatedly robs banks and then why would the
2 banks put a couple dollars in the charity box, is that
3 okay, for a doctor who is repeatedly writing illegitimate
4 prescriptions and knows that they are illegitimate and
10:08:05 5 continue to write, and to write a legitimate prescription
6 is possible.

7 Yes, sir, it's possible.

8 Q. Yeah, and, Mr. Catizone, with respect, that's not
9 what I'm saying.

10:08:20 10 I'm looking at it from the perspective of
11 the patient.

12 Is it possible that a patient can be in
13 need and go to a doctor that you would call a bad doctor
14 and get a prescription from that doctor that's valid?

10:08:32 15 A. It's possible, but I don't know why a patient would
16 go to a doctor that's involved in those activities and
17 harming other patients, sir.

18 Q. Well, we don't know what patients are going
19 through, right? We don't know what their pain is or why
10:08:44 20 they go to the doctor they go to. We don't know that.

21 I'm only asking you can a patient in need
22 go to what you would call a bad doctor and get a
23 legitimate prescription?

24 A. But I think in this situation you described, sir,
10:08:57 25 you said a pill-mill, and as you said earlier pharmacists

1 who are familiar with their patients and practice, if
2 this was a pill-mill and the patient went there for a
3 legitimate treatment instead of going to another doctor
4 at Cleveland Clinic or pain management, yes, it's
10:09:10 5 possible, but I don't know why a patient would go there
6 or why there would be a need to go there, sir.

7 Q. As a pharmacist, would you withhold treatment from
8 a patient who had a legitimate medical need because of
9 where he or she got the prescription?

10:09:25 10 A. If it was a legitimate prescription and the
11 prescriber was not a bad prescriber operating a
12 pill-mill, then yes, I would fill that prescription, sir.

13 Q. My question was more specific.

14 Would you refuse to fill a prescription for
10:09:40 15 a patient with legitimate medical need because that
16 patient had gone to a doctor that you personally believe
17 is a bad doctor?

18 Would you refuse that prescription?

19 A. Not necessarily, sir.

10:09:50 20 Q. Okay. Last topic.

21 Going back to the 2,000 sample
22 prescriptions from the Walgreen's data that you looked
23 at, I take it your opinion -- so I'll take it in bites
24 here.

10:10:12 25 I think you just said your opinion, all of

1 those were Dr. -- or between you and Dr. McCann you
2 determined that all of those 2,000 were red flags, right?

3 A. The prescriptions had either one or multiple red
4 flags, sir.

10:10:27 5 Q. And according to you, I think you also just said
6 none of those prescriptions should have been dispensed,
7 right?

8 A. I said the overwhelming majority of prescriptions
9 lacked the necessary documentation to resolve those red
10:10:38 10 flags to dispense the prescription, sir.

11 Q. And do you believe that some number of those
12 prescriptions were written by doctors not for legitimate
13 medical purpose?

14 A. Yes, sir.

10:10:46 15 Q. By a doctor violating the law?

16 A. Yes, sir.

17 Q. How many doctors in the Walgreen's data that you
18 reviewed do you contend were violating the law when they
19 wrote their prescription?

10:10:58 20 A. I didn't specifically review that. I just reviewed
21 the prescription, sir, I was presented.

22 Q. So sitting here today you can't tell me which of
23 those 2,000 prescriptions according to you was written by
24 a doctor for not a legitimate purpose, correct?

10:11:14 25 A. Correct, sir.

1 Q. And of those 2,000 doctors in the sample, did you
2 undertake any sort of analysis as to who the doctors are,
3 what hospitals they're affiliated with, what their
4 specialties are?

10:11:25 5 A. No, sir. I simply looked at the red flags and
6 whether they were resolved and documented by the
7 pharmacist to be resolved, sir.

8 Q. Okay. So in those 2,000 scripts written by those
9 doctors, you don't know how many work in hospice, right?

10:11:38 10 A. Yes. Well, based upon the notes, sir, I was able
11 to identify in some of the data as few as 16
12 prescriptions or 32 that actually had markings for
13 hospice or cancer in the data sets.

14 I'm not sure if that was specific to
10:11:52 15 Walgreen's, but less than one percent had any of those
16 types of markings or notes, sir.

17 Q. And I might have misheard.

18 You're saying of all the prescriptions you
19 looked at that was the number you came up with?

10:12:04 20 A. I know for one of the individual defendants, and
21 I'd have to check my report, it was only 16 and 32
22 prescriptions that had either hospice or cancer, and then
23 when I looked at all the prescriptions across the board
24 for all defendants it was probably less than one percent
10:12:18 25 that I could find that type of designation, sir.

1 Q. How many of those doctors worked for the Cleveland
2 Clinic or University Hospitals?

3 A. I again looked at the prescriptions to see how many
4 came from the Cleveland Clinic, and again, that was a
10:12:31 5 small percentage across all prescriptions, probably about
6 less than one percent or so.

7 And that was one of the exceptions we
8 talked about, that if it was from the Cleveland Clinic,
9 that may have resolved some of the red flags as long as
10:12:43 10 that was documented, sir.

11 Q. Well, sir, you're not telling me that you've done
12 an analysis of all the prescriptions you looked at and
13 can tell me what percentage came from Cleveland Clinic or
14 Lake Health, right? You're not telling me that?

10:12:54 15 A. Pretty much, sir. I've looked at all those
16 prescriptions, and if they noted Cleveland Clinic,
17 because I knew that was going to be an issue to look at,
18 I kept that total, and I would say it's less than, maybe,
19 five, five percent max across all prescriptions.

10:13:11 20 Q. What percentage of those doctors were orthopedic
21 surgeons who do hip replacements?

22 A. I didn't make that analysis, sir.

23 Q. What percentage were doctors, orthopedic surgeons,
24 who do knee replacements?

10:13:22 25 A. Didn't have that information, didn't conduct that

1 analysis, sir.

2 Q. How many were neck and spine surgeons?

3 A. Again, same answer, sir.

10:13:32

4 Q. How many doctors treated patients with rheumatoid
5 arthritis?

6 A. Same response, sir.

10:13:42

7 Q. Okay. That's something you couldn't tell by
8 looking at the face of the document, but a pharmacist
9 looking at his dispensing system would have that
10 information?

11 A. And I could have told if it was documented in the
12 notes.

13 Q. Well, but you didn't look at all the notes.

10:13:51

14 You looked at just the prescriptions that
15 were given to you by the plaintiffs' lawyers for
16 Walgreen's. You didn't look at the 150,000 files that
17 were also provided that might have had that information,
18 true?

10:14:00

19 A. I looked at all the prescriptions and the notes
20 that were provided to me for those prescriptions.

21 I don't know if that was part of the other
22 data you're referring to, sir, but there were notes in
23 patient information for the prescriptions I looked at.

10:14:12

24 Q. And what you looked at was what was provided to you
25 by the plaintiffs' lawyers, right?

1 A. Yes, sir.

2 MR. SWANSON: Okay. Thank you.

3 I don't have any other questions.

4 MS. SULLIVAN: If I may, Your Honor.

10:14:22 5 THE COURT: Yes. Mr. Fumerton for Walmart.

6 MS. SULLIVAN: No, Giant Eagle, Your Honor.

7 THE COURT: Oh, I'm sorry, it was

8 Ms. Sullivan.

9 MS. SULLIVAN: Yes.

10:14:40 10 CROSS-EXAMINATION OF CARMEN CATIZONE

11 BY MS. SULLIVAN:

12 Q. Good morning, jurors. Good morning, Dr. Catizone.

13 We haven't met yet. Diane Sullivan, and

14 I'm here for the folks at Giant Eagle. Good to meet you.

10:15:01 15 A. It's a pleasure to meet you. Thank you.

16 Q. If you could bear with me, I don't think I'll be
17 that long this morning.

18 I want to go back to the American Medical

19 Association resolution that you discussed with

10:15:12 20 Mr. Lanier, and I think with Mr. Swanson a little bit,

21 and that's the -- and that is in Tab 43, Mr. Catizone, of

22 the binder that Ms. Sampson just gave you.

23 MS. SULLIVAN: We're getting a copy for

24 Mr. Lanier. There we go.

10:15:52 25 And any objection, Mr. Lanier, to my

1 showing the jury the AMA resolution that was discussed?

2 MR. LANIER: I haven't seen it. I was just
3 handed it, but I don't think I've got any objection.

4 MS. SULLIVAN: Okay.

10:16:08 5 MR. LANIER: It looks legit to me.

6 MS. SULLIVAN: And, Mr. Pitts, if I could
7 have the Elmo. Thank you.

8 BY MS. SULLIVAN:

9 Q. All right. And, Dr. Catizone, this is the American
10:16:28 10 Medical Association resolution from 2013 that you were
11 discussing last week where the AMA basically told
12 prescribers "Don't second guess our medical decisions,"
13 right?

14 A. Can you tell me what page it's on, please?

10:16:43 15 Q. Oh, I'm sorry, sir. It's -- if you look at the
16 Bates Number on -- it's on the top of the page 443.

17 A. Thank you.

18 Q. Let me know when you have it.

19 A. Are you referring to D-35.9A1?

10:17:08 20 Q. It's on Page 443, on the top.

21 A. Right, but it says "House action, adopted as
22 follows"?

23 Q. Yes. Resolution 218, do you have it?

24 A. Yes.

10:17:17 25 Q. And, Mr. Catizone, this was the document you were

1 discussing last week where the American Medical
2 Association basically issued a policy document resolving
3 that it was inappropriate for pharmacies to inquire about
4 verifying medical rationale behind prescriptions, right?

10:17:37 5 A. My understanding is that this was adopted, but I'm
6 not sure it became policy with the AMA.

7 My understanding from the AMA attorneys
8 that we worked with, that it was nonbinding, but I can't
9 speak as to what it was, but it was passed by one of the
10:17:51 10 delegates of AMA or by the House of Delegates of AMA,
11 yes.

12 Q. Yes. We can pull it up, but do you know,
13 Mr. Catizone, if you go to the American Medical
14 Association's website and look up their policy documents,
10:18:07 15 this is an existing policy.

16 A. Okay.

17 Q. Okay. You don't dispute that?

18 I can have Roman do that if you'd like.

19 A. Nope, don't dispute. Just wasn't familiar with the
10:18:17 20 process.

21 Q. Okay. So, Mr. Catizone, according to the American
22 Medical Association's website, this is in 2021 an
23 existing policy of the Medical Association, okay?

24 A. Yes.

10:18:27 25 Q. And I think Mr. Lanier -- and I think maybe you

1 said that there are, you think, 39,000 doctors that are
2 part of the American Medical Association?

3 That's not right, is it, sir?

4 A. That was a guesstimate on my part.

10:18:43 5 I know there are two million licensed
6 prescribers. That's a definitive answer, but I don't
7 know how many members they have.

8 Q. In fact, if you look at the American Medical
9 Association's website, there's over 200,000 members of
10:18:54 10 the American Medical Association, right?

11 MR. LANIER: Your Honor, I'm going to
12 object to that.

13 A, I think it's wrong, and B, I think it
14 should be in evidence if she's going to be making
10:19:09 15 assumptions.

16 THE COURT: Sustained.

17 BY MS. SULLIVAN:

18 Q. The truth is, Mr. Catizone, you don't know how many
19 members there are of the American Medical Association?

10:19:18 20 A. I know the numbers reported sometimes don't reflect
21 the actual membership, and in discussions that I've had
22 even though it may be reported as 200,000, that may be a
23 generous number, is what I could say.

24 Q. And, Mr. Catizone, you know it is the largest
10:19:33 25 medical organization association in America?

1 A. I don't know that.

2 Q. No reason to dispute that?

3 A. I'm sorry, I didn't hear you.

4 Q. Do you know of a bigger one?

10:19:43 5 A. Than the AMA?

6 Q. Yes, sir.

7 A. The Teamsters.

8 Q. I'm talking about a medical -- yeah, the Teamsters
9 are way bigger, way bigger, way bigger.

10:19:53 10 I'm talking about no other medical
11 association bigger than the American Medical Association?

12 A. I'm not sure the family physicians, I'm not sure
13 what their membership is either.

14 Q. And I think Mr. Lanier told the jury this was a
10:20:05 15 resolution by the folks in New Jersey?

16 A. No, that was my comment.

17 Q. Okay.

18 A. I thought it was that.

19 Q. I apologize.

10:20:11 20 And, Mr. Catizone, you can see here that
21 this is actually a resolution proposed by a few medical
22 organization states, Connecticut, Maine, Massachusetts,
23 New Hampshire, Rhode Island, and Vermont, right?

24 A. Yes.

10:20:26 25 Q. I know people like to pick on New Jersey, but New

1 Jersey is not here, right?

2 A. No comment.

3 Q. And in fact, not only was it proposed by these
4 various medical associations in these several states, it
10:20:40 5 was adopted by the entire national medical organization,
6 correct, by the American Medical Association?

7 A. By the House of Delegates, yes.

8 Q. Yes. And it's an existing policy where even to
9 this day the American Medical Association says that it is
10:20:53 10 inappropriate for pharmacists to call to verify the
11 medical rationale about -- behind doctors' prescriptions,
12 right?

13 MR. LANIER: Objection, Your Honor. That
14 is not what it says.

10:21:03 15 Misrepresentation of the document.

16 THE COURT: I'll sustain. I'll sustain the
17 objection.

18 MS. SULLIVAN: I'm happy to read it if I
19 misread it, Mr. Catizone.

10:21:13 20 BY MS. SULLIVAN:

21 Q. It says that "Our AMA, the American Medical
22 Association, deem inappropriate inquiries from pharmacies
23 to verify the medical rationale behind prescriptions,
24 diagnoses and treatment plans to be an interference with
10:21:27 25 the practice of medicine and unwarranted."

1 Do you see that, sir?

2 A. Yes.

3 Q. So the AMA is saying, it deems it inappropriate
4 inquiries from pharmacies to verify medical rationale
10:21:46 5 behind prescriptions, diagnoses and treatment, right?

6 MR. LANIER: I still object, Your Honor.
7 That's not what it says.

8 It says --

9 THE COURT: It is not clear to me what this
10:21:56 10 document says, Ms. Sullivan, so -- the grammar is not
11 great, so --

12 BY MS. SULLIVAN:

13 Q. The grammar could be better, sir, but I think you
14 testified last week that essentially the AMA said to
10:22:10 15 doctors it is inappropriate inquiries from pharmacists to
16 verify the medical rationale behind prescriptions,
17 diagnoses, and treatment plans because they viewed that
18 to be an interference with the practice of medicine,
19 right? That was your testimony?

10:22:25 20 A. No, it wasn't.

21 My testimony was that the physicians were
22 objecting that the pharmacists were calling for MRI and
23 other x-rays, and that was my understanding.

24 The resolution calls for AMA to work with
10:22:36 25 pharmacy organizations and also to resolve the drug abuse

1 and diversion, which was my understanding of what the
2 result was of those communications.

3 Q. In fairness, Mr. Catizone, this doesn't say
4 anything about MRIs.

10:22:48 5 It says "Inquiries to verify medical
6 rationale behind prescriptions, diagnoses and treatment,"
7 right?

8 A. Correct. You asked me what my testimony was, and
9 that's what I provided back to you, ma'am.

10:22:58 10 Q. Okay. But this talks about inquiries about
11 prescriptions, right, in addition to medical diagnoses
12 and treatment?

13 A. That's what the resolution says, yes.

14 Q. And, Mr. Catizone, in fact you've acknowledged,
10:23:22 15 sir, that doctors have a lot more information than
16 pharmacists about medical records, patient history,
17 diagnostic tests, et cetera, right?

18 A. They have more patient information, but not drug
19 information.

10:23:34 20 Q. Yeah. They have a lot more medical information
21 about a patient?

22 A. Yes.

23 Q. And one of the things that doctors were concerned
24 about is that pharmacists second-guessing doctors would

10:23:49 25 put patient health at risk, that was part of what was in

1 the meeting minutes, et cetera, of the American Medical
2 Association?

3 They thought pharmacists by saying, no, I'm
4 not going to prescribe a medicine a doctor thought was
10:24:02 5 important, was putting patient health at risk.

6 Fair?

7 A. For me, I thought it was a -- based on the
8 information I had -- a turf battle. The doctors didn't
9 want pharmacists interfering or taking over any of their
10:24:16 10 responsibilities because there was issues and concerns
11 about payment as well, so --

12 Q. And patient health?

13 A. To some degree, yes.

14 Q. Yes. And, in fact, Doctor, the Federal Government,
10:24:30 15 you're familiar, and I think the jury's heard a little
16 bit about it, the Drug Enforcement Administration's
17 guidelines in the pharmacy manual?

18 A. I'm unfamiliar with the *Pharmacist's Manual*.

19 Q. Yeah. And the *Pharmacist's Manual*, and we can look
10:24:46 20 at it, was when the Drug Enforcement Administration sent
21 out a manual for pharmacists to use to try and make sure
22 they were complying with the Controlled Substances Act?

23 A. I think it was more of an educational resource
24 where it further defined corresponding responsibility and
10:25:04 25 said the doctors have a responsibility for that

1 prescription, for that patient, but pharmacists have a
2 corresponding responsibility to that physician's
3 responsibility, and pretty much set the ground for
4 pharmacists and doctors working together.

10:25:19 5 Q. Okay. Why don't we just look at what they -- why
6 don't we just look at what they say?

7 If we could put up starting with the 2004
8 *Pharmacist's Manual*, Defense Exhibit MDL 10863, that's
9 Tab 35.

10:25:35 10 A. Ma'am, is that in the packet?

11 Q. It's Tab 35, Mr. Catizone.

12 A. Thank you.

13 Q. Let me know when you have it, sir.

14 Do you have it, sir?

10:26:18 15 A. Yes, I do. I'm sorry.

16 Q. Okay. And if we can just look at it here on the
17 Elmo, in the sort of the introductory page --

18 MS. SULLIVAN: And I'm sorry, Ms. Sampson,
19 can you grab me a highlighter over there?

10:26:32 20 Thank you.

21 BY MS. SULLIVAN:

22 Q. -- the DEA is saying that "The manual is to assist
23 pharmacists in understanding the provisions of the
24 Controlled Substances Act and its implementing
10:26:48 25 regulations."

1 Right?

2 A. And to preventing diversion and abuse, yes.

3 Q. Yeah. Yeah. In other words, this was the DEA's

4 efforts to pharmacists, read our manual, here are

10:27:00 5 guidelines to assist you in complying with the Controlled

6 Substances Act, including trying to prevent diversion?

7 A. Yes, ma'am.

8 Q. Okay. And if we look at Page 84, Dr. Catizone, of

9 the federal government's -- the DEA's manual here to

10:27:21 10 pharmacists.

11 A. Yes.

12 Q. Okay. And what it says is, "Proper controls

13 against bogus prescriptions can best be accomplished by

14 following common sense, sound professional practice, and

10:27:44 15 proper dispensing procedures and controls."

16 Right?

17 A. Yes.

18 Q. So the DEA is saying you, pharmacists, have a job

19 in guarding against bogus illegitimate prescriptions,

10:27:59 20 right?

21 A. That's part of the message.

22 Q. Yeah. Yeah.

23 What the -- what the DEA is not saying is

24 that pharmacists should be second-guessing doctors'

10:28:09 25 legitimate prescriptions, that's not the pharmacist's

1 job, right, sir?

2 A. No, I think if you turn back to the beginning of
3 the document, and it's probably the second page --

4 Q. Sir, we're going to look at it, but I just want to
5 stick to this.

6 A. I'm trying to answer the question about -- because
7 you said was that the message.

8 There it says, "The DEA is greatly
9 concerned about the diversion and abuse of controlled
10 substances and drug products containing listed chemicals.
11 Most drug diversion occurs at the retail level where the
12 pharmacist plays a critical role in supervising the
13 proper control of prescription drugs, prescription and
14 over the counter drugs. Because the pharmacist dispenses
15 controlled substances to the patient, he or she is in a
16 key position to safeguard the health of the patient and
17 prevent diversion.

18 "The pharmacist and the prescribing
19 practitioner share responsibility for monitoring the
20 therapeutic drug usage of patients whose health depends
21 on concerned and knowledgeable professionals."

22 I think the DEA is saying that pharmacists
23 have to play an active role in preventing diversion and
24 questioning the therapeutic drug usage of those drugs.
25 It's right here in the manual, ma'am.

1 Q. Sir, it doesn't say they should be second-guessing
2 the medical judgment of doctors.

3 What page are you reading from,
4 Mr. Catizone?

10:29:32 5 A. That's the second page, it's listed as Roman
6 Numeral VI.

7 I think the second-guessing is a colloquial
8 term that the doctors have described what they believe
9 pharmacists are doing.

10:29:43 10 Pharmacists would say we're simply doing
11 what we're supposed to be doing.

12 Q. And when the -- when the DEA, in the *Pharmacist's*
13 *Manual*, Mr. Catizone, talks about policing bogus
14 prescriptions, it talks about pharmacists using their
10:30:04 15 common sense and sound professional practice and
16 judgment, right?

17 A. Yes.

18 Q. And the *Pharmacist's Manual*, you know, sir, that
19 the *Pharmacist's Manual* both in 2004, in 2010, and in
10:30:22 20 2020, lists criteria that may indicate that a
21 prescription was not issued for a legitimate medical
22 purpose, right?

23 A. But in context, this --

24 Q. Could you answer my question, sir?

10:30:34 25 A. To some degree, yes.

1 Q. Yes. So the -- so, in other words, the
2 *Pharmacist's Manual*, the DEA is trying to tell
3 pharmacists "Here's the things you look for, here are the
4 criteria" -- they call it criteria in the manual, right,
10:30:50 5 sir?

6 A. Yes.

7 Q. Okay. "Here are the criteria that may" -- that
8 may, not necessarily as you've said -- "may give rise to
9 a suspicious prescription," right?

10:31:01 10 A. For information at the time, yes.

11 Q. Yes. And when the Government, in 2004, and we can
12 pull out the 2020 edition, but it's the same six
13 criteria, do you know that, sir?

14 A. Yes.

10:31:14 15 Q. Okay. And so the Government lists six, what you
16 would call red flags, right, in the manual?

17 A. No. I think I would call these signs of forgery or
18 abuse or diversion.

19 The red flags are referenced in the 2020
10:31:30 20 manual and subsequent editions by footnotes to DEA cases
21 where those red flags have been identified.

22 Q. But we're going to look at that, but you talk about
23 forgery. That's a whole different section, right, sir?

24 If you look at the manual, forgery is a
10:31:48 25 whole different section?

1 A. Correct.

2 Q. Okay. But I'm sticking with the six what you would
3 say are red flags for potential diversion, right?

4 A. No.

10:31:54 5 I testified and didn't say they were red
6 flags.

7 If you look at the heading, it says
8 "Characteristics of forged prescriptions," so this
9 section back in 2004, before the opioid crisis really
10:32:03 10 hit, the primary concern of pharmacists and the DEA were
11 forged prescriptions or stolen prescriptions and,
12 therefore, the DEA said, here it is, here are some
13 characteristics.

14 In fact, they had a colloquial way to
10:32:17 15 remember it, it was the three Ds to look at doctors:
16 Duped, deception, and the third was doesn't know what
17 they're doing, basically.

18 So that's what they told pharmacists to
19 look for, forged or stolen prescriptions.

10:32:30 20 Opioids hadn't hit the fan yet.

21 Q. Doctor, can we look at the 2020 manual?

22 We can agree by 2020 the opioid crisis was
23 in full bloom?

24 A. Correct.

10:32:45 25 Q. So the 2020 *Pharmacist's Manual* that's Defense

1 Exhibit MDL 11598, that would be Tab 52.

2 A. I'm sorry, what tab?

3 Q. 52, sir.

4 And, Mr. Catizone, while you're looking for
10:33:05 5 that, we can agree that the 2020 *Pharmacist's Manual* came
6 out after the *Holiday* decision, the *Superior* 1 and 2
7 decision, and after the *Hills* decision that you talked to
8 the jury about, right?

9 A. Yes, ma'am.

10:33:19 10 Q. They were all years before the 2020 *Pharmacist's*
11 *Manual*?

12 A. Correct.

13 Q. And if we look, Mr. Catizone, in the 2020
14 *Pharmacist's Manual* on Page 114.

10:33:51 15 Let me know when you're there.

16 A. Yes.

17 Q. In addition to the section on fraudulent
18 prescriptions, and, Mr. Catizone, as I understand it, you
19 had 16 red flags in addition to fraud, in other words,
10:34:05 20 that's different than looking at forged prescription
21 pads, that wasn't one of your red flags?

22 A. That would be one of the aberrant behaviors of
23 patients but it wasn't one of the red flags that I had
24 the analysis for.

10:34:18 25 Q. Yes. And the DEA does the same thing.

1 They had six criteria plus, then they have
2 a section about forged prescriptions.

3 Do you see that?

4 A. Yes.

10:34:27 5 Q. Okay. But where you have 16 red flags, in 2020,
6 after these DEA decisions that you discussed with the
7 jury, the DEA lists six, right? Six criteria for
8 identifying potentially illegitimate prescriptions.

9 They list six.

10:34:54 10 A. No. Again, what the Pharmacist's --

11 Q. Sir --

12 A. I'm answering. The *Pharmacist's Manual*, what's
13 listed, these are fraudulent prescriptions or out of
14 scope prescriptions.

10:35:03 15 Q. No, sir. The fraudulent prescription section is
16 underneath.

17 A. I'm sorry, I thought you were referring to that.

18 Q. No. I'm looking at the criteria that the
19 Government says pharmacists should look at for
10:35:15 20 identifying illegitimate prescriptions.

21 A. Yes.

22 Q. Do you see that?

23 A. Yes.

24 Q. Okay. And they list six?

10:35:20 25 A. Yes.

1 Q. Okay. You have 16, they have six, fair?

2 A. There's other references where they refer to
3 Page 113 and Page 103.

10:35:36

4 Q. Sir, when they say, "Here are the criteria, here
5 are the red flags that pharmacists should look for" in
6 their manual instructing pharmacists about how to comply
7 with the Controlled Substances Act, they list six
8 important criteria that indicate that a prescription may
9 not be issued for a legitimate medical purpose. That's
10 what they say?

10:35:53

11 A. With all due respect, ma'am, as a pharmacist I
12 wouldn't read just one paragraph.

13 The whole document is important and other
14 references are in the document, ma'am.

10:36:03

15 Q. Okay. And I'm going to look at Tab 47. I want to
16 just take you back, Mr. Catizone, to the corresponding
17 regulation.

18 And I believe it's Tab 47, Ms. Sampson.
19 And the jury's seen this before.

10:36:46

20 This is -- and Dr. Catizone, you've
21 testified about it before?

22 A. Excuse me, ma'am. My monitor is not showing me.

23 Q. Oh, I'm sorry, your monitor went down, sir.

24 A. Yeah. But what document are you on?

10:37:01

25 Q. This is -- this is the Federal Regulation 1306.

1 A. What tab?

2 Q. This is Tab 47.

3 THE COURT: Tab 47.

4 THE WITNESS: Thank you, Your Honor.

10:37:20 5 A. Okay. I have it.

6 Thank you.

7 I've got it, yes. Thank you.

8 BY MS. SULLIVAN:

9 Q. Okay. And, Doctor, this is the federal regulation
10:37:44 10 that outlines the responsibilities of pharmacists,
11 correct?

12 A. Correct.

13 Q. And the regulation talks about the responsibility
14 for the proper prescribing and dispensing of controlled
10:37:54 15 substances is upon the prescribing practitioner.

16 That's the first part, right?

17 A. Yes.

18 Q. But the corresponding responsibility rests with the
19 pharmacist who fills the prescription, right?

10:38:04 20 A. Yes.

21 Q. And it goes on to say that a prescription that's
22 not in the usual course -- that means an illegitimate
23 prescription, right?

24 A. Yes.

10:38:14 25 Q. That a pharmacist should not knowingly fill such a

1 prescription, right?

2 A. Yes.

3 Q. Okay. That's the responsibility, don't knowingly
4 fill an illegitimate prescription.

10:38:26 5 That's what the law says?

6 A. There's a -- yes.

7 Q. Okay. And in talking about signs that a
8 prescription may be illegitimate, may be bogus, I think
9 we can look at your report, but you've acknowledged that
10:38:49 10 this concept of concerns or suspicions or red flags goes
11 back for decades, that pharmacists are educated on these
12 potential red flags in pharmacy school, for example?

13 A. Yes.

14 Q. And it's on the multi-state test that pharmacists
10:39:04 15 take?

16 A. Yes.

17 Q. And it's generally well known to pharmacists what
18 to look for, they're trained on it in pharmacy school,
19 they're tested on it, what to look for in determining
10:39:17 20 whether a prescription is illegitimate or not?

21 A. Yes.

22 Q. And, in fact, I think you've said it's common sense
23 for a pharmacist?

24 A. Well, part of knowing is common sense, yes.

10:39:31 25 Q. And in other words, red flags or concerns about

1 potential illegitimate prescriptions is something that
2 every pharmacist is trained on and knows?

3 A. Yes.

4 Q. And I just want to ask you, it's your view that if
10:40:00 5 a pharmacist does the right thing, checks the Government
6 database, the OARRS data to see if a patient has sought
7 opioids from another doctor, and called the prescriber,
8 basically cleared a red flag, if that effort is not
9 documented, I think it was your testimony it doesn't
10:40:19 10 count?

11 A. No.

12 It was my testimony that they haven't met
13 the requirements for resolving and documenting that red
14 flag.

10:40:25 15 Q. But it still happened.

16 In other words --

17 A. If you don't document it, how do you know it
18 happened.

19 Q. Okay. Well, if I spent two days cleaning my house
10:40:34 20 and nobody takes my picture or videos me, that doesn't
21 mean I didn't clean my house?

22 A. But somebody has to come in and see your house. If
23 your house what you consider is clean is not clean to
24 someone else, lack of documentation like in the pharmacy,
10:40:50 25 the documentation is the key to other pharmacists knowing

1 that you cleaned your house.

2 Q. Is that a comment on my housekeeping skills,
3 Mr. Catizone?

10:41:00

4 A. Not at all. I've learned to be quiet on those
5 issues.

6 Q. But, Doctor, the truth is a pharmacist could do
7 everything right and clear a red flag, but not document
8 it?

9 A. Then they didn't do everything right.

10:41:13

10 Q. That's your view?

11 A. That's my expert opinion based upon 40 years and
12 based upon thousands of prescriptions and cases that I've
13 worked on in this regard.

10:41:24

14 Q. And, Doctor, there's a video that you talk about in
15 your expert report, it's an anti-diversion video, I think
16 you were proud of, and it's used to train pharmacists on
17 how to spot and evaluate red flags?

18 A. If you're referring to the red flag video, yes.

10:41:41

19 Q. Yes. And it actually was part of the
20 anti-diversion task force and your organization, the
21 National Association of Pharmacy Boards, worked together
22 to put this out to pharmacists to help them evaluate and
23 spot concerns or red flags?

24 A. The organization I formerly was in charge of, yes.

10:41:56

25 Q. And in fact you were on the web introducing that

1 video as --

2 A. What I did is I introduced the video and then each
3 individual state Executive Director of the Board of
4 Pharmacy did a little introduction as well for them.

10:42:09 5 Q. And you would think it would be a good thing if
6 companies like Giant Eagle, Walgreen's, CVS, Walmart, if
7 they used that video to train their pharmacists in how to
8 evaluate and clear red flags?

9 A. Yes.

10:42:20 10 Q. And, Dr. Catizone, the truth is that that video
11 says absolutely nothing about the requirement to document
12 red flags?

13 A. I can't recall the entire video, so I'd like to
14 have a chance to look at it again.

10:42:37 15 If it doesn't, it talks about corresponding
16 responsibility, so --

17 Q. Do you know, sir? I mean, we can --

18 A. I'd be glad to watch it if you'd like.

19 Q. Yeah. Do you know, sir, it says absolutely nothing
10:42:47 20 about documenting or clearing red flags?

21 A. I believe it probably specifically doesn't say
22 document, but I'm sure it talks about corresponding
23 responsibility and identifying red flags.

24 Q. Sir, do you know it says absolutely nothing about
10:42:59 25 the need to document?

1 A. I've agreed with you it probably doesn't
2 specifically say that, but it's inherent to what
3 corresponding responsibility is.

10:43:14

4 Q. Okay. Mr. Catizone, you talked about some of the
5 work you've done with the Drug Enforcement
6 Administration?

7 A. Yes.

10:43:24

8 Q. And the Drug Enforcement Administration, and I
9 think you've mentioned some of this, they have -- they
10 have tools or tests or metrics that they use to try to
11 determine whether a dispensing or distribution is
12 suspicious?

13 A. I'm not aware of those metrics and I haven't seen
14 those metrics in any of the cases I've worked.

10:43:41

15 Q. Maybe my question was poor, but you mentioned, for
16 example, that one thing that people look at is how much
17 cash business you're doing in terms of opioid and how
18 people are paying, paying for opioids?

10:43:56

19 A. Correct. Those are the established red flags that
20 prior DEA actions have defined, yes.

21 Q. Yeah. Yeah. And it's one of the metrics that DEA,
22 one of the tests that DEA uses to determine whether
23 there's suspicious activity, how much -- how much of a
24 pharmacy's business is cash as it relates to opioids?

10:44:11

25 A. Yes. It's one of the factors they look at.

1 Q. Yes. And that's not one of the tests that you
2 applied here.

3 In other words, you did not look at Giant
4 Eagle's prescriptions and opioids and to figure out what
10:44:25 5 percentage was cash or not?

6 A. What I did is I looked at the cash prescriptions to
7 see if there was a note explaining why, but I did not
8 look at the percentage that you just described.

9 Q. Yes. So in fairness, Mr. Catizone, you did not
10:44:38 10 apply that Government test to Giant Eagle?

11 In other words, you didn't look at what
12 percentage of Giant Eagle's controlled substance
13 dispensing was paid for by cash?

14 A. Correct.

10:44:50 15 Q. Okay. And you didn't do that for any of these
16 companies?

17 A. Correct.

18 Q. And in fact, Mr. Catizone, there's a whole bunch of
19 tests that the Government looks at to determine whether
10:45:05 20 pharmacies are engaged in potentially suspicious
21 diversion activities?

22 A. I'm uncomfortable when you say there's a number of
23 tests without knowing what those tests are, but I'm sure
24 that the Government has things that they look at that may
10:45:18 25 be different than what I looked at as a pharmacist, yes.

1 Q. And I think you've mentioned one.

2 What -- so one of the things the Government
3 or the Drug Enforcement Administration looks at is what
4 percentage of the medicines you're dispensing are
10:45:33 5 controlled substances versus noncontrolled substances
6 versus regular prescriptions?

7 A. I've seen that in other documents, I've seen it
8 opined more so for distributors as well, but, yes, I've
9 seen that metric used before.

10:45:47 10 Q. And, Mr. Catizone, that's also a test that you did
11 not use here?

12 A. It was data that I didn't look at or analyze, yes.

13 Q. Okay. In other words, you didn't look at what
14 percentage of Giant Eagle's prescriptions were controlled
10:46:01 15 substances versus noncontrolled substances, regular
16 medicines?

17 A. Correct.

18 Q. And you didn't do that for any of the other
19 pharmacies either?

10:46:09 20 A. Correct.

21 Q. And another test or metric that the Drug
22 Enforcement Administration looks to to see if a business
23 or a pharmacy is perhaps engaged in diversion or
24 suspicious activity is what percentage of high dose
10:46:27 25 opioids they're prescribing versus other opioids?

1 A. That metric I'm not familiar with.

2 I haven't seen that metric applied.

3 Q. Okay. And you didn't -- so you didn't apply that
4 here either?

10:46:39 5 A. Correct.

6 Q. And, Doctor, I want to talk a little bit about
7 Giant Eagle.

8 You know, Dr. Catizone, that Giant
9 Eagle -- Mr. Catizone, you'd like to be called Mister or
10 Doctor, or --

11 A. Either way is fine.

12 The Doctor is a designation conferred on me
13 by the State of Oklahoma based upon my work. It's more
14 honorary.

10:47:13 15 My family doesn't respect me or call me
16 Doctor, so you can call me Mister if you'd like.

17 Q. Mr. Catizone, you know that Giant Eagle is not a
18 national chain?

19 A. Is not?

10:47:27 20 Q. Is not.

21 A. It's a regional chain.

22 Q. Yes.

23 A. Yes.

24 Q. You know that they don't have thousands of stores
10:47:34 25 across the country?

1 A. Correct. Yes, I do know that.

2 Q. And, Mr. Catizone, do you know which states they
3 operate in?

10:47:46

4 A. I'm not specifically sure but I know it's more of
5 the Mid-Atlantic, but I'm not sure.

6 Q. You don't know which states they operate in?

7 A. No.

8 Q. Do you know they don't have any operations in
9 Florida?

10:47:55

10 A. No. I don't know that.

11 Q. You don't know that?

12 Okay. So when you reviewed information
13 about this case, were you not told that Giant Eagle only
14 has stores in five states?

10:48:11

15 A. What I was asked to do is review the prescriptions
16 from Giant Eagle based upon the red flags that presented,
17 whether or not Giant resolved those red flags and
18 documented those red flags, and that's what I was asked.

10:48:26

19 I wasn't asked to do any corporate analysis
20 or analysis of the footprints of those chains in the
21 country or in the various states.

22 Q. But I think the jury heard you give some opinions
23 about Florida pill-mills and people trafficking pills
24 from Florida and other states into Ohio.

10:48:41

25 Do you remember talking about that?

1 A. I think that was raised by one of your colleagues
2 asking if I knew about pill-mills and knew about the
3 preponderance of pill-mills in Florida, and I simply said
4 yes, that was known in pharmacy.

10:48:52 5 Q. And do you know, sir, that Giant Eagle has no
6 stores in Florida?

7 A. I didn't know that but I'm not sure it made any
8 difference or would make any difference to my opinion.

9 Q. Do you know, sir, that Giant Eagle pharmacies
10:49:04 10 are -- in Lake and Trumbull County are all in grocery
11 stores?

12 A. Yes.

13 Q. And as I understand it, you didn't talk to any
14 Giant Eagle pharmacists as part of your review in this
10:49:15 15 case?

16 A. No.

17 Q. Either current pharmacists or former pharmacists?

18 A. No.

19 Q. And you didn't talk to any of the doctors that
10:49:22 20 prescribed the prescriptions that you looked at?

21 A. No.

22 Q. And you didn't talk to any patients --

23 THE REPORTER: I'm sorry, could you hold on
24 for one second?

10:49:53 25 MS. SULLIVAN: Sure. Sorry, Sue.

1 THE COURT: Ms. Sullivan, if you're about
2 to conclude or ready to wrap up, let me know if it's a
3 good time to take a break.

4 MS. SULLIVAN: It's a good time to take a
10:50:03 5 break, Your Honor.

6 THE COURT: Ladies and gentlemen, we're
7 going to take our break. You might eat a few more snacks
8 because we're going to go longer today and then take a
9 lunch.

10:50:15 10 (Jury out.)

11 (Recess taken.)

12 (Jury in.)

13 THE COURT: Okay. Please be seated.

14 And, Ms. Sullivan, you may continue. And,
11:11:15 15 Dr. Catizone, just reminding you you're still under oath.

16 THE WITNESS: Yes, sir.

17 MS. SULLIVAN: Thank you, Your Honor.

18 BY MS. SULLIVAN:

19 Q. Mr. Catizone, I want to shift gears and talk about
11:11:24 20 the time metric slide you put up that you were talking
21 about how companies put a time in terms of wait times.

22 Do you remember that slide?

23 A. Yes.

24 Q. Okay.

11:11:36 25 A. I don't think it was a slide.

1 It was a discussion about some of the
2 markings I saw on the hard copies, I believe.

3 Q. Okay. I thought it was on a PowerPoint, too, but
4 in any event, you talked about Giant Eagle having a
11:11:50 5 15-minute wait time.

6 Do you remember that?

7 A. No, I think it was in reference to CVS.

8 Q. Sorry?

9 A. I think it was in reference to CVS. I don't think
11:11:58 10 I spoke about Giant Eagle in that regard.

11 Q. Okay. Fair enough. So you didn't say
12 anything -- so it's not your opinion that Giant Eagle set
13 a certain wait time for people?

14 A. That's my understanding.

11:12:07 15 Q. They did not?

16 A. Correct.

17 Q. Okay. I just want to clear that up. So when you
18 were talking about companies who had, you know, certain
19 wait times, you had to rush out prescriptions, Giant
11:12:17 20 Eagle did not have a fixed wait time?

21 A. That's my understanding.

22 Q. And you did, Mr. Catizone, talk about I believe
23 Giant Eagle and bonuses and prescription volume.

24 Do you remember that?

11:12:32 25 A. I'm sorry, you went a little fast. I didn't hear

1 any of the question.

2 Q. Do you recall your testimony about Giant Eagle and
3 prescription bonuses based on volume of prescriptions?

4 A. What I testified was the metrics that the various
11:12:46 5 policies have, and Giant Eagle had certain metrics as
6 well.

7 Q. And I wanted to -- and I believe you showed the
8 jury this document -- I want to just put it back up, if I
9 could.

11:12:55 10 It's Exhibit 9546, if I can get it here.

11 And that would be Tab 27, Doctor, if you want to get a
12 hard copy.

13 A. Okay. I have it.

14 Q. Okay. And I want to start by looking at the
11:13:31 15 pharmacists on Page 2.

16 A. Okay.

17 Q. And I believe you were critical of Giant Eagle by
18 having a bonus system that was in some way tied to
19 prescription unit volume.

11:13:47 20 Do you remember that?

21 A. My testimony was that that impacted the
22 pharmacist's ability to conduct due diligence, yes.

23 Q. Yeah. And I just wanted to talk a little bit more
24 about that.

11:13:57 25 So do you see, sir, that the pharmacist

1 bonus is based on their salary, right?

2 A. No, I don't think it's based upon their salary.

3 It's based upon the salary for -- the
4 salary cost within the budget was my understanding.

11:14:14 5 Q. Well, do you see the top line says "Based upon the
6 salary at the beginning of the fiscal year," right? The
7 bonus percentage is based upon the salary at the
8 beginning of the fiscal year, that's what it says, sir,
9 right?

11:14:27 10 A. Yes.

11 Q. And it says the maximum you can get is one percent
12 of your salary, right?

13 A. That's -- yes.

14 Q. And the maximum based upon prescription unit volume
11:14:36 15 is one percent, right?

16 A. Yes.

17 Q. And in 2014, the average salary for a pharmacist
18 was roughly \$100,000?

19 A. Yes.

11:14:44 20 Q. Okay. So if the average salary for a pharmacist is
21 \$100,000, and prescription volume, that's all
22 prescriptions, right, in the store? That's just not
23 opioids?

24 A. That would be my understanding, yes.

11:14:59 25 Q. Okay. And do you know what percentage of

1 prescriptions Giant Eagle dispensed in 2014 were
2 noncontrolled substances?

3 A. I think you asked that earlier and the answer is
4 no.

11:15:12 5 Q. Okay. So if I told you that Giant Eagle's ratio
6 was 90 percent noncontrolled substances and 10 percent
7 controlled substances including opioids, you would have
8 no reason to dispute that?

9 A. No.

11:15:24 10 Q. Okay. So if you take -- if Giant Eagle is doing 10
11 percent of controlled substances, including opioid, then
12 the volumetric for opioid prescriptions or controlled
13 substance prescription would be one-tenth of one percent,
14 right?

11:15:40 15 A. No.

16 Q. Well, if they're doing 10 percent of their
17 prescriptions are for noncontrolled substances, that
18 would be one-tenth of one percent of the volume, fair?

19 A. Not fair.

11:15:52 20 What you're making --

21 Q. I'm sure you're going to get a chance to explain
22 and you can explain to me, but I just want to, if I can
23 just get an answer to my question, sir?

24 THE COURT: The answer was "Not fair."

11:16:02 25 Okay.

1 A. Not fair.

2 Q. But it's true, sir, that if only 10 percent of
3 Giant Eagle's prescriptions are for controlled
4 substances, that would be one-tenth of one percent of the
11:16:13 5 volume bonus?

6 A. No.

7 Q. Okay. So, and, Doctor, you know this is
8 store-wide, right? This is just not for the one
9 pharmacist.

11:16:32 10 Do you know the prescription volume is
11 calculated store-wide?

12 A. Yes.

13 Q. Okay. And it's calculated based on total volume,
14 including noncontrolled substances?

11:16:43 15 A. Correct.

16 Q. Okay. So the one percent includes both opioid
17 prescriptions and nonopioid prescriptions?

18 A. Correct.

19 Q. Okay. And if Giant Eagle's nonopioid prescriptions
11:16:56 20 are 90 percent and their controlled substance
21 prescriptions, including opioids, are 10 percent, that
22 would be one-tenth of one percent of the total volume
23 bonus?

24 A. No.

11:17:08 25 Q. Okay. You and I do math differently, Doctor.

1 But if I'm right that's a hundred dollars?

2 A. It's not math. It's pharmacy practice, and I don't
3 believe you're right, with all due respect.

4 Q. And if it's -- the prescription unit volume
11:17:25 5 includes all of the prescriptions, opioids and
6 nonopioids, right?

7 A. You're -- yes.

8 Q. Okay?

9 A. The answer is still no because you're not
11:17:34 10 approaching it the right way.

11 Q. Okay. I got it.

12 I want to turn to do you know, sir, that
13 Giant Eagle got rid of the prescription volume bonus such
14 as it was in 2016?

11:17:54 15 A. No.

16 Q. So when you were giving opinions criticizing that
17 kind of bonus, you did not know that Giant Eagle had
18 eliminated it?

19 A. I looked at the information and the prescription
11:18:07 20 volumes, and if they had it in place up to 2016 then
21 there was probably six years' worth of that bonus.

22 Q. Do you know, sir, that Giant Eagle produced to the
23 plaintiffs dispensing data for almost 1.4 million
24 prescriptions?

11:18:27 25 A. Again, I reviewed the sample scripts from all the

1 defendants that were provided to me.

2 I didn't know what the total universe was.

3 Q. So you -- and as I understand it, sir, you reviewed
4 2,000 prescriptions for Giant Eagle?

11:18:42 5 A. Approximately, yes.

6 Q. And so you didn't review 1.2 million prescriptions?

7 A. No.

8 My understanding was that the defendants
9 provided a random sample and those 2,000 prescriptions
11:18:56 10 would give an indication of what that 1.2 represented
11 without having to look at all 1.2 million.

12 Q. Okay. But the 2,000 Giant Eagle's prescriptions
13 you reviewed is a fraction of one percent of the total
14 prescriptions?

11:19:08 15 A. It's a representative sample of the entire sample.

16 Q. A small fraction of less than one percent?

17 A. I didn't do the math, but it's supposed to be in
18 terms of what it is, it's a representative sample of
19 everything Giant Eagle dispensed.

11:19:23 20 Q. And, Mr. Catizone, as I understand it, you did not
21 look to see how many of the patients who received the
22 2,000 prescriptions that you looked at were already
23 existing patients of Giant Eagle pharmacies?

24 A. No. My understanding the way you've asked the
11:19:44 25 question, no.

1 Q. Okay. So you don't know if they were customers who
2 had a long history with Giant Eagle, patients?

3 A. If it was in the notes, then I knew that. If it
4 wasn't in the notes, then I didn't know that.

11:19:55 5 Q. And if I told you that 90 percent of the
6 prescriptions that you looked at of the 2,000 involved
7 existing Giant Eagle pharmacy patients, you could not
8 dispute that?

9 A. Well, since you and I disagreed on math before, I'm
11:20:11 10 not sure I would take that, but I'd have to give it to
11 you, so --

12 Q. And I think you talked to Mr. Swanson and
13 Mr. Lanier about the fact that pharmacists get to know
14 their patients, they get to know the doctors, and they
11:20:26 15 have familiarity with the patients, with the patients
16 they serve?

17 A. Correct. Yes.

18 Q. In terms of their -- the medicines they've been
19 prescribed, their doctors, and often their conditions,
11:20:39 20 right?

21 A. Correct.

22 Q. And I want to just look at, if I could, some of the
23 demonstrative slides that you put up as related to Giant
24 Eagle.

11:21:00 25 Doctor, the first one is in Tab 37.

1 A. I have that, thank you.

2 Q. You got it? Okay.

3 And I think you said that 54 percent of the
4 2,000 scripts you looked at for Giant Eagle didn't have
5 notes, right?

6 A. Correct.

7 Q. But then when you looked at the hard copy of the
8 prescription, which were different than the computer, the
9 pharmacist actually did put notes in about -- in many of
10 those?

11 A. Yes. The slide said 782 of the prescriptions did
12 not contain any information in the notes and any
13 handwritten documentation on the hard copy, so of the
14 1,094 there were some notations on the remaining roughly
15 1,300.

16 Q. Okay. So of the 2,000 sample that you looked at,
17 over 60 percent of the Giant Eagle prescriptions did have
18 notes from the pharmacists?

19 A. It had markings or something, but not relevant
20 notes, no.

21 Q. And looking at the notes that you put up for
22 our -- for our jurors, I just want to go back to those,
23 if I could.

24 And, Doctor, there's a notes database that
25 was produced that you looked at in connection with these

1 prescriptions, right?

2 A. I was provided spreadsheets for all the defendants
3 with all of the notes and some hard copy prescriptions as
4 a JPEG, yes.

11:22:39 5 Q. And I want to put up, if I could, Defense Exhibit
6 HBC/GE MDL 00178, and that's the notes field for one of
7 the prescriptions that was in your demonstrative.

8 A. What tab is that, please?

9 Q. That would be in Tab 38.

11:22:58 10 A. 30?

11 THE COURT: 30 or 38?

12 MS. SULLIVAN: 38.

13 THE COURT: 38.

14 Thank you, Ms. Sullivan.

11:23:04 15 MS. SULLIVAN: Sure.

16 A. I've got it.

17 BY MS. SULLIVAN:

18 Q. Okay. And this is the -- an example of the kinds
19 of notes fields you look at, right, sir?

11:23:22 20 A. Yes.

21 Q. Okay. And what it has is it has the year that the
22 prescription you looked at was dispensed, right?

23 A. Correct.

24 Q. And then it has the notes that the pharmacist wrote
11:23:35 25 in here, right?

1 A. Correct.

2 Q. And it has a sample number for the patient, right,
3 or for the prescription, I'm sorry.

4 Do you see that?

11:23:45 5 A. Yes.

6 Q. Okay. And one of the problems that you pointed out
7 in your expert report is that when you pull up the
8 prescription that was dispensed, you get notes for a
9 whole bunch of things that have nothing to do with that
10 prescription, right?

11 A. Correct.

12 Q. In other words, if we look at this, it talks
13 about -- it talks about a prescription from 2012, from
14 2016, from other dates, but the prescription that was
15 dispensed is 2010, right?

16 A. Yes.

17 Q. Okay. So and you cited that in your report as a
18 problem, as an issue?

19 A. Correct.

11:24:25 20 Q. So in other words, when you're looking at these
21 notes, you can't assume this has anything to do with the
22 prescription that was dispensed?

23 A. That was one of the comments I made in my report as
24 well.

11:24:34 25 Q. Yeah. So when you're telling the jury that this

1 means that this -- this note means that this prescription
2 was dispensed, that's not necessarily true because it
3 could relate to a completely different prescription?

11:24:52

4 A. No. The reason this prescription is in the sample
5 is it had more than one flag.

6 I can't recall specifically, but I think
7 this prescription had six or seven red flags.

8 Q. So, Doctor, I think you're missing my question.

11:25:05

9 The prescription that was dispensed is
10 2010, right?

11 A. Correct.

12 Q. But the notes relate to prescriptions in 2012 and
13 2016?

14 A. Correct.

11:25:12

15 Q. And you don't have any evidence that those were
16 actually dispensed?

17 A. No. My comment was that the prescription issued in
18 2010 that had the multiple red flags for which there are
19 no notes was dispensed.

11:25:27

20 Q. But, Doctor, you showed the jury, and we'll put it
21 up, these are the examples of the red flags, but they
22 relate to completely different prescriptions?

23 A. I don't know that.

11:25:39

24 Q. But the dates are two years apart, the dates are
25 two years apart, the dates are four years apart?

1 A. Part of the problem is the prescription numbers
2 were not included in the notes.

3 I had no idea if this related back to that
4 original prescription that was filled in 2010, if this
11:25:52 5 was a new prescription, or if this was an ongoing problem
6 with the patient.

7 That's the reason documentation is critical
8 in these situations.

9 No one knows what these notes mean. All I
11:26:02 10 know is that prescription had multiple red flags in 2010.
11 Those red flags were not resolved. That prescription was
12 dispensed. And now we've got notes for 2012 citing
13 there's some other significant issues.

14 Don't know what that related to, and even
11:26:18 15 those issues then I don't know how those were resolved as
16 well.

17 Q. But, Doctor, part of the problem here is that we
18 know the 2010 prescription was dispensed, that's the one
19 you looked at, right?

11:26:27 20 A. Yes.

21 Q. But then you talked to the jury about all of these
22 other notes that have nothing to do with the 2010
23 prescription?

24 A. Again, as I've just discussed, there were no notes
11:26:39 25 related to the 2010 prescription that had multiple red

1 flags.

2 These notes appeared in that section.

3 Either the pharmacist just was putting random notes in

4 that section for that prescription, or significant

11:26:53 5 documentation is missing that is intelligent people in

6 this room probably could figure out what happened or what

7 that note means, and we still don't know what happened to

8 the red flags for that prescription in 2010 that was

9 actually dispensed.

11:27:09 10 Q. But, Doctor, part of the problem is you put up this

11 slide, you and your lawyer.

12 Did you create these slides or did the

13 plaintiffs' lawyers?

14 A. The plaintiffs' lawyers did.

11:27:17 15 Q. They did. Okay.

16 So the plaintiffs' lawyers created these

17 slides for you with what you talked about as red flags,

18 right, that have absolutely nothing to do with the

19 prescription that was dispensed?

11:27:29 20 A. I --

21 Q. Isn't that a problem? Isn't that misleading, sir?

22 A. I respectfully disagree with you.

23 This was in that patient profile under that

24 notes, under those notes, for this prescription.

11:27:39 25 If it was not appropriate, it was not

1 appropriate on the part of Giant Eagle and their
2 pharmacists for not including that documentation as it
3 should have been, or they made a huge mistake including
4 documentation for another prescription that shouldn't
5 have been in there.

6 That's a significant problem. That's
7 something that's very dangerous for the patients.

8 Q. Doctor, isn't it a significant problem for the
9 plaintiffs' lawyers to put up notes that -- for
10 prescriptions that you have no idea were dispensed or
11 not?

12 The pharmacists could have refused to
13 prescribe these things, could have refused to fill these
14 prescriptions, and you have no idea.

15 Fair? Can you answer that? You have no
16 idea that these notes that the plaintiffs' lawyers
17 decided to put up for you relating to 2012 and 2016 have
18 anything at all to do with the 2010 prescription?

19 A. Not fair.

20 Q. Okay. You have no evidence, Doctor, do you have
21 any evidence that the 2012 and 2016 prescriptions
22 referred to in these PowerPoints were actually dispensed
23 by Giant Eagle?

24 A. The evidence I have --

25 Q. Can you answer that question, sir? Can you --

1 A. Yes.

2 Q. -- answer whether you have any evidence that these
3 2012 and 2016 prescriptions that you guys talked about to
4 the jury were actually filled?

11:29:01 5 A. My answer is yes.

6 Q. You -- and where is that, Doctor? Because the only
7 ones that are filled according to this was the 2010 one.

8 A. There's no evidence to indicate that these were
9 different prescriptions whatsoever.

11:29:16 10 Q. Doctor -- I'm sorry.

11 A. I'm sorry, you asked for evidence, ma'am, and I'm
12 trying to answer your question.

13 Q. No evidence even though the years are two years
14 different, four years different, right?

11:29:26 15 A. Part of the problem I found with the prescription
16 data set is that people were on opioids for multiple
17 years, so it doesn't surprise me that a prescription
18 originally dispensed in 2010, that a patient would still
19 be on that and that the pharmacist would attach notes to
11:29:41 20 that prescription.

21 Why would the pharmacist include notes for
22 different prescriptions in a note file for that
23 prescription unless it was an ongoing prescription? And
24 so, yes, the evidence to me is that same prescription
11:29:54 25 dispensed in 2010 was dispensed in 2012 and again in

1 2016, based upon the notes and documentation I was
2 provided.

3 Q. Doctor, in looking at the next slide that the
4 plaintiffs' lawyers -- did the plaintiffs' lawyers create
11:30:14 5 all these slides for you?

6 A. I just responded yes.

7 Q. They're the ones that picked these out to talk
8 about?

9 A. Those were all part of my report, and they took
11:30:22 10 excerpts out of my report. So I picked those out
11 originally and the plaintiffs' attorneys put those
12 together for a presentation to explain things to the
13 jury.

14 Q. So this is the same exhibit number, but Tab 40.

11:30:37 15 A. Okay. I have it.

16 Q. And, doctor, this relates to your slide 63 and 64,
17 it's the same patient.

18 Do you see that?

19 Do you have your slides? I'll put them up
11:30:50 20 for you, but these are slides that you talked to the jury
21 about, 63 and 64.

22 A. Okay.

23 Q. And it relates to a March 16th, 2011 prescription,
24 your slides do, anyway.

11:31:00 25 Do you see that?

1 A. No. It refers to that prescription in 2010.

2 Q. But the dates in these notes are March 11th, that
3 says "Absolutely no early refills," right?

4 A. Correct.

11:31:13 5 Q. "No more filling," right?

6 A. We're back to the same situation we just discussed.

7 Q. We are back to the same situation, sir.

8 But if you look at the notes for this

9 prescription, it's actually two different prescriptions,

11:31:24 10 right? We've got two different index numbers, do you see
11 that?

12 A. Sometimes different index numbers were front and
13 back of the prescription, so without looking at these I
14 couldn't -- I can't tell you specifically.

11:31:33 15 Q. You don't know that this refers to, these two
16 different numbers means these are two different
17 prescriptions?

18 Do you know that, sir?

19 A. What numbers are you utilizing?

11:31:44 20 Q. I'm looking at, if you go in Tab 40, I'm looking at
21 the prescription notes that correspond to the slides you
22 showed the jury.

23 A. Aren't those all the same date, 65?

24 Q. No, sir. Look at 15352.

11:32:06 25 A. Okay.

1 Q. Do you see that? Do you see those are two
2 different prescriptions, right? Okay. You didn't tell
3 the jury those are two different prescriptions, did you,
4 sir?

11:32:14 5 A. No, I thought that that would be understood, so --

6 Q. Okay. And the prescription again that was filled
7 was 2010, do you see that, sir?

8 A. Yes.

9 Q. But again, the notes relate to years 2011, right?

11:32:31 10 A. Yes.

11 Q. And do you know, sir, in fact that Giant Eagle did
12 not fill this prescription in 2011?

13 Do you know that, sir?

14 A. I do not know in 2011, but the evidence would
11:32:42 15 indicate since it was part of the note for 2012 that it
16 probably was dispensed.

17 Q. Sir, do you have any evidence that the March 16th,
18 '11 note, that this prescription was actually dispensed?

19 A. The evidence I have is what's been provided by
11:32:57 20 Giant Eagle.

21 There's the prescription, 2012. There's
22 notes surrounding that prescription, and as the defense
23 has said, information's in there that they've been
24 documenting. I took that as saying this prescription was
11:33:10 25 dispensed every single time that those dates appeared.

1 Q. Yeah, you assume that, but the record actually says
2 it was dispensed in 2010, right?

3 Do you see that?

4 A. Yes.

11:33:20 5 Q. And it was dispensed in 2012, do you see that?

6 Do you see that, sir, if you look at the
7 prescription database?

8 A. It says 3/16/11 and 3/1/11 for --

9 Q. No, sir, I'm looking at the actual database that
11:33:37 10 says what was dispensed.

11 Do you see that? It says it was
12 dispensed --

13 A. I'm sorry, can you tell me which one you're on?

14 Q. Sure. I'm looking at the database for the notes.

11:33:47 15 Do you see they match up here, sir?

16 A. No, I know that, but which one are you looking at
17 8865 or 15352?

18 Q. I'm looking at both of them. I'm looking at the
19 prescription that was dispensed, the 15 --

11:34:00 20 THE COURT: Hold it. Hold it.

21 Ms. Sullivan, I think you've established
22 they are two different prescriptions.

23 MS. SULLIVAN: Yes, sir.

24 THE COURT: The witness just wants to know
11:34:07 25 which prescription you're referring to.

1 MS. SULLIVAN: Well, Your Honor, I was
2 looking at both, but we can start with 15352.

3 BY MS. SULLIVAN:

4 Q. Do you see that?

11:34:13 5 A. Yes.

6 Q. Okay.

7 A. That was not dispensed in 2012, according to the
8 notes. That was dispensed in March of 2011.

9 Q. No, sir.

11:34:22 10 So, do you know, sir, that the left-hand
11 column means the prescription was dispensed? Do you know
12 that?

13 A. That was my understanding of the notes.

14 Q. Okay. And there is no note in the column that says
11:34:33 15 the prescription was dispensed, there's no 2011 for this
16 prescription, is there?

17 A. Not in that column, but in the notes column.

18 Q. Okay. In the notes column it says "No more
19 filling," right?

11:34:47 20 A. Correct.

21 Q. "No more discount cards."

22 In the notes column it says "No early
23 fills," right?

24 A. Correct.

11:34:54 25 Q. And in the column that tells you what was actually

1 filled, there is no evidence that this prescription was
2 filled in 2011.

3 Fair?

4 A. No.

11:35:03 5 Q. Okay. So, Doctor, do you know, sir, do you know
6 that this is the database that shows what was actually
7 dispensed?

8 A. That's my understanding, yes.

9 Q. And in terms of what was actually dispensed, the
11:35:26 10 years we have in this database relating to these two
11 prescriptions are 2010 and 2012, right?

12 A. And the notes section as well.

13 Q. But what was actually dispensed, there's no 2011,
14 it doesn't say anything was dispensed in 2011 if that's
11:35:42 15 not in that column?

16 A. If you'd allow me to explain I can explain my
17 answer.

18 Q. I'm sure Mr. Lanier will let you explain, but we
19 can agree that in the column that says "Concretely here's
11:35:52 20 what the pharmacist dispensed," there is no entry for
21 2011 for this prescription?

22 A. I disagree.

23 Q. Okay. Is that the kind, Doctor, is that the kind
24 of analysis you did for the other 2,000 prescriptions,
11:36:07 25 too?

1 A. That thorough analysis, yes.

2 Q. Okay. Terrific.

3 Can we -- I think I'm about done, Doctor.

4 And, Doctor Catizone, just because you

11:36:27 5 flagged a prescription or had Mr. -- Dr. McCann flag a

6 prescription under your 16 red flags does not mean that

7 it was written for an illegitimate purpose.

8 Fair?

9 A. Fair.

11:36:39 10 Q. And you agree it does not mean, just because Dr.

11 McCann and you flagged these, some of these prescriptions

12 under your 16 red flags, that does not mean that the

13 prescription was diverted?

14 A. Correct.

11:36:54 15 MS. SULLIVAN: I have nothing further.

16 Thank you, Dr. Catizone.

17 THE WITNESS: Thank you.

18 THE COURT: All right. Thank you,

19 Ms. Sullivan.

11:36:59 20 I think Mr. Delinsky, you're up?

21 MR. DELINSKY: Thank you, Your Honor.

22 THE COURT: This is Mr. Delinsky for CVS.

23 MR. HYNES: Your Honor, may I approach for

24 a moment to hand up documents?

11:37:15 25 THE COURT: Sure.

1 MR. DELINSKY: May it please the Court.

2 THE COURT: Yes, Mr. Delinsky.

3 CROSS-EXAMINATION OF CARMEN CATIZONE

4 BY MR. DELINSKY:

11:37:53 5 Q. Jurors, Mr. Catizone, my name is Eric Delinsky, and
6 I represent CVS in this case.

7 A. Nice to meet you, sir.

8 Q. It's nice to meet you, too. As a matter of fact,
9 we shook hands outside, right?

11:38:05 10 A. Yes, sir.

11 Q. But no conversations other than hello?

12 A. Yes, sir.

13 Q. Okay. Mr. Catizone, in response to questions put
14 to you by several lawyers, you discussed noncontrolled
11:38:19 15 medications.

16 Do you recall that?

17 A. Yes, sir.

18 Q. Noncontrolled medications are medications that are
19 not scheduled by the U.S. DEA, correct?

11:38:32 20 A. Correct, and the states as well, sir.

21 Q. They are not as susceptible to potential abuse as
22 controlled substances?

23 A. Yes, sir.

24 Q. Okay. And noncontrolled medications include heart
11:38:48 25 medicine?

1 A. Diabetes medications, yes, sir.

2 Q. Okay. Blood pressure medication?

3 A. Yes, sir.

4 Q. Cholesterol medicine?

11:38:57 5 A. Yes, sir.

6 Q. Asthma medicine?

7 A. Yes, sir.

8 Q. And there's a lot of other kinds of noncontrolled
9 medications, correct?

11:39:03 10 A. Yes, sir.

11 Q. Now, on the flip side, we have controlled
12 medications also known as controlled substances, correct?

13 A. Yes, sir.

14 Q. And the opioid medications that are the subject of
11:39:18 15 your opinions are one of these controlled medications,
16 correct?

17 A. Yes, sir.

18 Q. There are several other types of controlled
19 substances or controlled medications as well, correct?

11:39:31 20 A. Outside of the five Schedules, sir?

21 Q. I'm sorry, I don't think my question -- that's my
22 bad.

23 In addition to opioid medications, there
24 are other classes of medications that are categorized as
11:39:49 25 controlled substances?

1 A. Yes, sir.

2 Q. For instance, Benzodiazepines, correct?

3 A. Yes, sir.

4 Q. Testosterone, correct?

11:39:58 5 A. Yes, sir.

6 Q. Stimulants, correct?

7 A. Yes, sir.

8 Q. And there's other kinds of medications that are
9 deemed controlled substances?

11:40:07 10 A. Correct.

11 Q. So opioid medications are just one of the several
12 kinds of controlled medications that are out there,
13 correct?

14 A. Yes, sir.

11:40:16 15 Q. Okay. And being an expert in the field as you are,
16 it would not surprise you to learn that for the CVS
17 Pharmacies in Lake and Trumbull County, approximately
18 87.5 percent of the prescriptions they filled were for
19 these noncontrolled medications?

11:40:48 20 A. Yeah, I have nothing, no reason to dispute or doubt
21 that, sir.

22 Q. Okay. Before we go any further, just some really
23 quick housekeeping questions. Okay?

24 A. Yes, sir.

11:41:00 25 Q. Since you left the stand on Friday, you did not

1 discuss your testimony with any of the counties' lawyers,
2 correct?

3 A. Correct.

4 Q. And since you left the stand on Friday, you didn't
11:41:16 5 discuss any issues that came up in your testimony or that
6 could come up, that could come up in your testimony with
7 any of the counties' lawyers?

8 A. Correct, sir.

9 Q. And you did not review any materials since you left
11:41:29 10 the stand on Friday, correct?

11 A. No, sir.

12 I reviewed my materials at home, but not in
13 conjunction with counsel or not at the direction of
14 counsel. Just for my preparation, sir.

11:41:42 15 Q. Okay. And what materials did you review,
16 Mr. Catizone?

17 A. I reviewed my report that was submitted on May,
18 2021, and then the supplemental report that was submitted
19 thereafter.

11:41:53 20 Q. Okay. Fair enough. Thank you, Doctor.

21 I get spun around on Doctor and Mister, So
22 I guess I'll probably vacillate between them both.

23 You testified on Friday about this
24 15-minute fill time, correct?

11:42:12 25 A. Yes, sir.

1 Q. That was in connection with my client CVS?

2 A. Yes, sir.

3 Q. And you testified that CVS asks its pharmacists to
4 fill prescriptions in 15 minutes or less?

11:42:30 5 A. Yes, sir. And I think part of the testimony was
6 that was in one of the documents that said -- that
7 distinguishes CVS from the other pharmacies, sir.

8 Q. Okay. You did not base this part of your opinion
9 on any testimony provided by a CVS pharmacist in this
11:42:47 10 case, correct?

11 A. I read depositions from the CVS pharmacists as part
12 of that, and that I had direct interactions in my role at
13 NABP where I've received information about that, sir.

14 But not part of the testimony.

11:43:11 15 Q. Do you have your report with you?

16 A. Yes, I do.

17 Q. Mr. Catizone, could you please turn to Page 94?

18 A. The supplemental report, sir, or the first report?

19 Q. The first report.

11:43:36 20 A. Okay, sir, I'm there.

21 Q. Okay. You have footnotes here, correct?

22 A. Yes.

23 Q. And this is the page of the report where you talk
24 about the 15-minute fill time, correct?

11:43:52 25 A. Yes, sir.

1 Q. And you don't cite any excerpts of any depositions
2 of any CVS witnesses, correct?

3 A. Correct.

4 Q. Okay. As you said in your testimony last week, you
11:44:06 5 based your opinion on this 15-minute fill time on a CVS
6 document, correct?

7 A. Correct.

8 Q. And, Mr. Catizone, if you could please pull up
9 20695.

11:44:28 10 A. Okay. I have that here, sir.

11 Q. This is the document about which you testified on
12 Friday, correct?

13 A. Yes, sir.

14 Q. And I believe you testified about Page 18 in
11:44:45 15 particular. I'll flip there. You can flip as well.

16 And I'm using the -- there's a lot of
17 different numbers on this. I'm using the one in the
18 bottom right corner.

19 A. I've got that, sir, yes.

11:44:57 20 Q. For page numbers. Okay.

21 Okay. This -- I'm sorry -- this is
22 Page 18. This was one of the pages you testified about,
23 correct?

24 A. Yes, sir.

11:45:07 25 Q. And you testified about this chart that contains

1 guidance on the 15-minute wait time, correct?

2 A. Yes, sir.

3 Q. Okay. Mr. Catizone, you appreciate that this
4 15-minute wait time is for patients who choose to wait in
5 the pharmacy for their prescription to be filled,
6 correct?

7 A. Yes, sir.

8 Q. Okay. As a matter of fact, on Page 19 of this
9 document, it says that.

10 It says, "Many of our customers choose to
11 wait in-store for their prescriptions, either because
12 they need a medication immediately or because they are
13 unable to return at a later time."

14 Correct?

15 A. Yes, sir.

16 Q. So this 15-minute time period pertains to what CVS
17 terms as -- in this document as "waiters," correct?

18 A. Yes, sir.

19 Q. The patients who either need their medicine right
20 away or can't come back later, and, therefore, hand the
21 prescription to the pharmacist and wait to get their
22 medicine back, correct?

23 A. Yes, sir.

24 Q. Okay. Now, you understand that CVS treats
25 non-waiters differently, correct?

1 A. Yes, sir.

2 Q. Okay. I think it's self-explanatory, but
3 non-waiters are patients who choose not to drop off their
4 prescription and wait for it to be filled, correct?

11:46:57 5 A. Yes, sir.

6 Q. Non-waiters can have their prescription, for
7 instance, phoned in by their doctor, and then they drop
8 by the pharmacy to pick it up later that day or maybe the
9 next day, correct?

11:47:10 10 A. Yes, sir.

11 Q. Or non-waiters can be patients who drive by the
12 pharmacy in the morning, hand the pharmacist or the
13 pharmacist technician her prescription, and then return
14 after work at the end of the day, correct?

11:47:24 15 A. Yes, sir.

16 Q. And you understand that for patients who don't
17 wait, for non-waiters, CVS sets no time at all, imposes
18 no guidance at all for how long pharmacists may take to
19 review and potentially fill those prescriptions, correct?

11:47:48 20 A. Yes, sir.

21 Q. So in that instance, when we're talking about
22 non-waiters, a pharmacist could set a wait time of 45
23 minutes, correct?

24 A. Yes, sir.

11:48:03 25 Q. The pharmacist could set a wait time of one hour?

1 A. Yes, sir.

2 Q. The pharmacist could set a wait time of two hours,
3 correct?

4 A. Correct, sir.

11:48:11 5 Q. The pharmacist could even set a longer wait time,
6 correct?

7 A. Yes, sir.

8 Q. Okay. And in that instance, when we're dealing
9 with a patient who is not a waiter, and the pharmacist
11:48:23 10 sets that wait time to be an hour or two hours, or
11 whatever that pharmacist thinks is appropriate, that's
12 not Domino's Pizza, correct?

13 A. Yes, sir. It's not, yeah.

14 Q. Okay. So again, we have two buckets on this
11:48:53 15 15-minute time limit.

16 We have the waiters. That's the kind of
17 patient to whom the 15-minute guidance applies, correct?

18 A. Yes, sir.

19 Q. And then we have the non-waiters, and the 15-minute
11:49:07 20 goal does not apply to them, correct?

21 A. Yes, sir.

22 Q. Okay. And you know that CVS pharmacists have the
23 flexibility to determine that a waiter should be treated
24 as a non-waiter?

11:49:31 25 A. I'm not understanding that question, sir, so

1 perhaps you could help me understand it, please.

2 Q. You know that if a patient comes to the pharmacy
3 and drops off a prescription and says, "I want to wait
4 for it," that the pharmacist, the CVS pharmacist, has the
11:49:51 5 flexibility to say, "I'm sorry, I know you want to wait,
6 but I can't handle this on a waiter basis; I'm going to
7 convert you to a non-waiter and you're going to have to
8 come back and pick it up at some later time"?

9 A. My question, to understand just what you're asking,
11:50:10 10 sir, is if you have the two buckets as you describe, the
11 waiter and non-waiter, and if the people coming in as
12 waiters need that prescription immediately or within that
13 15-minute time period, if the pharmacist then says
14 "You're a non-waiter," then does that count for the
11:50:30 15 pharmacist bonus calculation and metrics that that person
16 has been moved to the non-waiter, or what impact then do
17 those metrics have on the pharmacist, and then what if
18 the patient refuses to go to the non-waiting bucket?

19 Q. So I believe you've asked -- you've answered my
11:50:46 20 question with more questions.

21 A. Correct.

22 Q. Pretty common among lawyers, but you're not one,
23 but you're close to one.

24 My question is simply, you appreciate, do
11:50:57 25 you not, that the pharmacist, the CVS pharmacist, has

1 great flexibility in how to treat a patient so that if
2 the CVS pharmacist looks at a prescription and says it's
3 not appropriate for me to endeavor to fill that in 15
4 minutes, they can set a longer wait time, they can
11:51:17 5 categorize that patient as a non-waiter?

6 You understand that, correct?

7 A. Understand that, but I would say as a pharmacist
8 it's not a great flexibility.

9 I would say it's a limited flexibility
11:51:30 10 based upon the patient's needs and some of the other
11 restrictions that the pharmacist has placed upon them,
12 sir.

13 Q. You understand that when pharmacists exercise this
14 flexibility to tell a waiter, "I'm going to need more
11:51:49 15 time," that they can set whatever time they think is
16 appropriate?

17 A. Again, sir, as a pharmacist in real situations
18 that's very difficult to do, particularly if a patient
19 doesn't want to be a non-waiter or if the patient is ill
11:52:08 20 and wants to get home as quickly as possible.

21 So there's not that much flexibility for
22 the pharmacist to set any time they want. There's some,
23 sir, but not to say "Please come back in two hours" if
24 the patient can't come back in two hours.

11:52:21 25 Q. And you raise a very, very good point.

1 Being a pharmacist is difficult and
2 stressful at times, correct?

3 A. Almost as much as testifying, yes, sir.

4 Q. I imagine you were as good a pharmacist as you are
11:52:39 5 a testifier.

6 A. Well, thank you, but --

7 Q. But being a pharmacist isn't being in a laboratory,
8 correct?

9 A. Correct, sir.

11:52:48 10 Q. Because you have to deal with real life patients?

11 A. And people's lives, yes, sir.

12 Q. Correct. And when you're dealing with people and
13 human beings, sometimes you get ones who are just
14 impatient and don't want to wait and are angry, correct?

11:53:08 15 A. Yes, sir.

16 Q. And that's difficult for the pharmacist?

17 A. Yes, sir.

18 Q. And sometimes you're dealing with people who need
19 medicine immediately; they're in discomfort and they need
11:53:19 20 treatment, correct?

21 A. Yes, sir.

22 Q. And that limits the pharmacist's flexibility,
23 correct?

24 A. Yes, sir.

11:53:26 25 Q. So by way of example, if a roofer -- and I'm just

1 pulling this out of thin air, okay? -- fell from the roof
2 and suffered a very significant bone break and has just
3 been treated in the emergency room and has gotten a
4 prescription for an opioid medication, that person may
11:53:52 5 need that prescription pretty quickly, correct?

6 A. Yes, sir.

7 Q. Because that person is in intense discomfort,
8 correct?

9 A. Yes, sir.

11:54:00 10 Q. Okay. So the limitations on deviating from the
11 15-minute fill time to some extent are dictated by the
12 patient and the patient's individual needs and
13 circumstances?

14 A. Yes, sir.

11:54:16 15 Q. Okay. Let's come back to CVS and CVS's policies.

16 CVS gives the pharmacists flexibility on
17 that 15-minute fill time such that the pharmacists, if
18 they are able to or if the patient needs it, the
19 pharmacist can endeavor to fill in 15 minutes, but if
11:54:42 20 they don't, if the patient doesn't need it on that time
21 frame, and the pharmacist feels he or she needs more
22 time, she has the flexibility within CVS to convert that
23 patient from a waiter to a non-waiter and set a much
24 longer time to evaluate and process that prescription,
11:55:05 25 correct?

1 A. In concept, I would agree with you, but I did not
2 see anything in the information that specifically
3 addressed that in the policies and procedures.

4 All I saw was the 15-minute time limit, but
11:55:17 5 I didn't see anything that rewarded the pharmacist for
6 that or gave pharmacists that discretion.

7 Q. Correct. And this brings us back to where we began
8 on this.

9 You didn't review any testimony in this
11:55:32 10 case from a CVS employee or a CVS pharmacist about how
11 this works, correct?

12 A. I'm -- I've read the depositions, but I can't
13 recall everything, sir, so --

14 Q. Okay. Fair enough.

11:56:08 15 It's taken me awhile, I'm looking for
16 Lanier's -- Mr. Lanier --

17 MR. DELINSKY: Excuse me, Mark.

18 Q. -- Mr. Lanier's slides.

19 MR. LANIER: It's okay, Delinsky.

11:56:21 20 THE COURT: You can leave that last name,
21 too. It's okay.

22 BY MR. DELINSKY:

23 Q. You testified about several of the notes you
24 analyzed that were written by CVS pharmacists, correct?

11:56:36 25 A. Yes, sir.

1 Q. Okay. I'm not going to go through them all.

2 I think it would be tedious for everyone,

3 but I just want to go through a few, okay?

4 A. Yes, sir.

11:56:48 5 Q. This is one of the notes you testified to when

6 Mr. Lanier, or Lanier, was asking questions of you.

7 Do you recall that?

8 A. Yes, sir.

9 Q. Okay. And this, this is one of the notes you
11:57:15 10 reviewed of the 2,000 sample notes from CVS that was

11 prepared by CVS pharmacists in connection with a

12 prescription he or she filled for an opioid medication,
13 correct?

14 A. Yes, sir.

11:57:30 15 Q. And this note indicates that the pharmacist ran an
16 OARRS report, correct?

17 A. Yes, sir.

18 Q. Okay. And running an OARRS report is a good thing,
19 correct?

11:57:49 20 A. Yes, sir.

21 Q. Okay. I believe in the stakeholders report you
22 testified about this morning, it was called valuable,
23 correct?

24 A. Valuable and necessary, sir.

11:58:00 25 Q. You're right. You're right, Mr. Catizone. It said

1 valuable and necessary.

2 And just to orient everyone on what an
3 OARRS report is, an OARRS report is a report, it comes
4 from a database maintained by the State of Ohio Board of
11:58:17 5 Pharmacy, correct?

6 A. Yes, sir.

7 Q. And the pharmacist has the ability to log on and
8 get the prescription history maintained by the State
9 Board of Pharmacy for the particular patient that the
11:58:35 10 pharmacist is filling a prescription for in the moment,
11 correct?

12 A. And any other state data where that patient may
13 have had their prescription dispensed outside of Ohio.

14 Q. And that's absolutely correct.

11:58:49 15 So Ohio, by way of example, has an
16 agreement with Pennsylvania, so when you log on, if you
17 have a Trumbull County patient for instance, that patient
18 may be filling prescriptions at one time or another in
19 Pennsylvania since it's right over the line, correct?

11:59:03 20 A. Correct.

21 Q. And in Ohio, when you pull up this, this OARRS
22 report, you get both?

23 A. Yes, sir.

24 Q. Okay. But this pharmacist did a good thing by
11:59:15 25 running an OARRS report, correct?

1 A. That's what it looks like, sir, yes.

2 Q. Okay. Now, the language that you testified about
3 was what follows the last Rx, and that's shorthand for
4 prescription, correct?

11:59:30 5 A. Yes, sir.

6 Q. The last prescription was filled for the same drug
7 at Walgreen's for the same day supply and quantity.

8 Correct?

9 A. Yes, sir.

11:59:41 10 Q. And you identified that as a red flag for potential
11 pharmacy shopping, correct?

12 A. Yes, sir.

13 Q. And the concern with pharmacy shopping, among
14 others, is that a patient may be filling overlapping
11:59:55 15 prescriptions, correct; getting more pills than that
16 patient may need, correct?

17 A. Correct.

18 Q. Okay. Now, you also testified that you did not
19 know what AMCE is, correct?

12:00:09 20 A. Yes, sir.

21 Q. Okay. So you didn't know, first of all, that the
22 letters are wrong; it's ACME, that's a typo.

23 You wouldn't have known that?

24 A. I had no way of knowing that, sir.

12:00:24 25 Q. Okay. And you didn't know that ACME is Active

1 Cumulative -- I'm going to screw this up -- Morphine
2 Equivalent dose?

3 You didn't know that, correct?

4 A. I've never seen that definition anywhere, no, or
12:00:47 5 acronym. Yes, sir.

6 Q. Okay. And you didn't know that this is an acronym
7 that's used in OARRS, did you?

8 A. No.

9 Q. And you didn't know that what ACME means on OARRS
12:01:02 10 or what it does on OARRS is it gives a score, and it
11 advises the pharmacist how much of the prior opioid
12 prescription should be left at that point in time based
13 on the days supply?

14 You didn't know that, correct?

12:01:21 15 A. I'm familiar with the algorithm because I was
16 involved in the creation of the algorithm that the PDMPs
17 use, sir.

18 Q. Okay. So you do know, then, that when you have
19 these ACME algorithms, if the score is really high, that
12:01:38 20 means there's this patient has -- still has pills from
21 her last prescription?

22 A. What the algorithm tells the pharmacist is that the
23 potential for abuse and diversion is much higher and that
24 the pharmacist has to take a significant look at the
12:01:57 25 patient.

1 Scores in the 600 to 900 range indicate
2 that in the OARRS report. Middle scores say this may be
3 problematic. And then low scores assure or provide the
4 pharmacist with a guide to say this looks like a
12:02:11 5 relatively safe dispensing.

6 Q. I think we're talking about two different kinds of
7 scores, and I appreciate it's tough to keep them
8 straight.

9 You're talking about the NarxCare score,
12:02:24 10 correct?

11 A. Correct.

12 Q. And the NarxCare score in fact was built off a
13 platform which NABP pioneered and began to develop before
14 selling to a company called Appriss, correct?

12:02:39 15 A. Correct. That's what the basis for OARRS is and we
16 took it, we worked with the Ohio Board of Pharmacy and
17 incorporated that nationally. So much of what OARRS does
18 is based on NarxCare and NARxCHECK score, sir.

19 Q. Okay. This ACME score is different from the
12:02:57 20 NarxCare score because what it's telling the pharmacist,
21 it's very specific, is how many Morphine equivalents does
22 this patient still have based on their last prescription.
23 Okay?

24 A. Yes.

12:03:08 25 Q. And if that score is high, that means this patient

1 has leftover pills, and that's a danger sign, correct?

2 A. Yes, sir.

3 Q. But if the score is low, that means that if the
4 patient followed the instructions, the proper dosing
12:03:25 5 instructions on her last prescription, there's nothing
6 left over, it's not an early fill, right?

7 A. Not that it's not an early fill, but there's no
8 left over.

9 Q. Okay. And here, coming back to here, we took a
12:03:39 10 little detour and I apologize for that, but when we come
11 back to here, the pharmacist is writing down here and
12 indicating, "I looked at this ACME score and I determined
13 that it was zero."

14 Correct?

12:03:52 15 A. Yes, sir.

16 Q. And what that means is that the patient shouldn't
17 have had any leftover pills, correct?

18 A. So far, yes, sir.

19 Q. Okay. And what this pharmacist was able to learn
12:04:11 20 from the ACME score was that the prior prescription fill
21 at Walgreen's wouldn't overlap with the current
22 prescription that she was trying to fill or he was trying
23 to fill at CVS, correct?

24 A. That's what it says, but the following information
12:04:36 25 sort of conflicts with that, and if they made an error on

1 the abbreviation, then I'm a little bit concerned about
2 whether the zero is correct as well, because the next
3 part says that they filled it at Walgreen's, "Watch for
4 pharmacy shopping, always check OARRS," which indicates
12:04:53 5 that there's something going on here, instead of saying
6 "AMCE equals zero, no overlap, no problem."

7 Q. I think that's precisely right, Mr. Catizone.

8 Because what this pharmacist was doing was
9 saying there is no concern here, I'm going to fill it,
12:05:11 10 but I'm a little bothered by the pharmacy shopping piece.
11 I'm a little bothered by the fact that one was filled at
12 Walgreen's, the patient probably properly used that
13 prescription, but now she's coming to CVS. So even
14 though this is appropriate for me to fill, I am going to
12:05:30 15 be extra careful and include additional notations saying
16 that we should always check OARRS and that we should be
17 on the lookout for that.

18 That's good notetaking, correct?

19 A. In that explanation, yes, sir.

12:05:40 20 Q. All right. Before we move off this, you're aware
21 that this prescription was for a 15-day supply, correct?

22 A. I don't remember specifically, but I would take
23 your word for it, sir.

24 Q. Okay. And it wouldn't surprise you to know that
12:06:03 25 the daily strength for this prescription was 15 MME?

1 A. The strength would have to be in milligrams, sir.
2 The MME is how much of the Morphine was actually in the
3 system, so I don't know what the strength was.

12:06:24

4 Q. But the daily MME, it wouldn't surprise you to
5 learn that the daily MME in this prescription was 15?

6 A. Not surprise me. I just don't recall that.

7 Q. Okay. And that's fair. There's a lot of data
8 here.

9 A. Right.

12:06:33

10 Q. But assuming that it was 15, that would be within
11 the CDC guidelines for MMEs, correct?

12 A. Yes, sir.

13 Q. And that doesn't solve all potential problems with
14 a script but it's an indicator, correct?

12:06:49

15 A. I don't know how many red flags were associated
16 with this prescription, sir, as you just said.

17 Q. And you don't know, and I know you're going to
18 testify why you don't know, okay, but you don't know what
19 the patient's condition was here or why her doctor
12:07:14 20 prescribed this medication, do you?

21 A. No, sir.

22 Q. Okay. And you would say you don't know that
23 because it's not written down here, correct?

24 A. And was not also on the hard copy.

12:07:25

25 Q. Okay. But the fact that it wasn't reduced to paper

1 and written down does not mean that the pharmacist didn't
2 know that information, correct?

3 A. Correct.

4 Q. Let's look at another example. I'll try to make
12:07:48 5 this simple.

6 I'm copying this technique of using white
7 pages from Mr. Lanier.

8 This is another slide you testified about,
9 correct?

12:07:59 10 A. Yes, sir.

11 Q. And this is another note by a CVS pharmacist that
12 raised concerns for you, correct?

13 A. Yes, sir.

14 Q. And the concern is that the note here says "Watch
12:08:11 15 fake CII," correct?

16 A. Yes, sir.

17 Q. Okay. And this is the computer note, correct?
18 This comes from the computer fields that you looked at,
19 correct?

12:08:25 20 A. Yes, sir.

21 Q. And for the ladies and gentlemen of the jury, CII
22 is a reference to a Schedule II controlled substance,
23 correct?

24 A. Yes, sir.

12:08:35 25 Q. And generally speaking, Schedule II controlled

1 substances include the opioid medications that we've been
2 talking about in this case, correct?

3 A. Yes, sir.

4 Q. Okay. Now, you know that this prescription was
12:08:52 5 only for a five-day supply, correct?

6 A. I don't recall that, sir.

7 Q. Fair enough. Take my word for it?

8 A. Yes, sir.

9 Q. Okay. And you know that the -- that MME on this
12:09:06 10 prescription was, for those five days, was 20?

11 A. I would have to take your word again, sir.

12 Q. Okay. And that would be consistent with a
13 prescription for something acute maybe, correct?

14 A. Possibly, yes.

12:09:18 15 Q. Okay. Beyond this, when you testified about this
16 note on Friday, you testified about this computer note,
17 but you didn't testify about the handwritten notes that
18 the pharmacist made on the prescription, correct?

19 A. Yes, sir.

12:09:44 20 And the problem and disconnect is -- if you
21 could put up the spreadsheet -- because each of these
22 prescriptions, even though we can resolve some of what's
23 happening on the surface or with these notes, each of the
24 examples I gave had six or more or five or more red flags
12:10:01 25 that weren't resolved.

1 So this is one aspect of it. It would be
2 very helpful, sir, if I could see that spreadsheet and we
3 could go through each of those red flags to make sure
4 that each of those were resolved and not just this
12:10:12 5 immediate.

6 We talked last week about some of the
7 prescriptions just on their face looked like they were
8 okay until I looked at the other red flags that existed
9 with that prescription, sir.

12:10:21 10 Q. Sir, would you please look at CVS MDL 02487?

11 A. Yes, sir.

12 Q. Okay. And I will represent to you that this is the
13 hard copy prescription that accompanied the note we're
14 looking at, "Watch fake CII."

12:10:51 15 A. Yes, sir.

16 Q. Okay. Now, you would have reviewed this note,
17 correct, or this prescription?

18 A. Right. I would have looked at the spreadsheet and
19 looked at all the red flags that this prescription had,
12:11:04 20 and then I would have looked at this hard copy, sir.

21 Q. Okay. And this prescription shows that it came
22 from the emergency department, do you see that?

23 A. Yes, sir.

24 Q. And it says "Minor emergency department," but we
12:11:24 25 know this patient was not a minor because her date of

1 birth or his date of birth was 1977, correct?

2 A. Yes, sir.

3 Q. Okay. If you look on the reverse side of the
4 prescription, we then have pharmacist's notes, correct?

12:11:41 5 A. Yes, sir.

6 Q. Handwritten notes?

7 A. Yes, sir.

8 Q. And the pharmacist says, "OARRS checked," correct?

9 A. Yes, sir.

12:11:53 10 Q. And again, that is a valuable and, in your words,
11 necessary step, correct?

12 A. Yes, it's necessary, yes, sir.

13 Q. Okay. This was a good effort on the part of this
14 pharmacist to get this script from the emergency

12:12:09 15 department and then pull up OARRS to check on the
16 patient, correct?

17 A. Yes, but in accordance with CVS policies where they
18 give specific examples of documentation that was not
19 acceptable and it was in my report, things such as

12:12:25 20 reviewed, check with M.D., check OARRS, was designated by
21 CVS as not approved, and then CVS provided recommended
22 language on how to document those types of activities,
23 sir.

24 Q. 100 percent, CVS wants a lot of documentation, no
12:12:42 25 doubt about it, but what you just testified about was the

1 quality of the documentation, correct?

2 A. Correct.

3 Q. I want to talk about the quality of the work the
4 pharmacist did.

12:12:52 5 And by checking OARRS, that was good
6 quality work, correct?

7 A. Yes, sir.

8 Q. Okay. And the pharmacist says that this is a new
9 patient, correct?

12:13:05 10 A. Yes, sir.

11 Q. So the pharmacist is noting that.

12 And the pharmacist is then saying -- then
13 adds, "Also note to watch patient with controls."

14 Correct?

12:13:19 15 A. Yes, sir.

16 Q. So this pharmacist is saying, "I have a
17 prescription from the emergency department," correct?

18 A. Yes, sir.

19 Q. The pharmacist is saying, "I've checked OARRS,"
12:13:30 20 correct?

21 A. Yes, sir.

22 Q. "This is a new patient who I'm not familiar with,"
23 correct?

24 A. Yes, sir.

12:13:36 25 Q. "I'm deciding to fill this prescription from an

1 emergency department that's only for five days and is
2 relatively low MME," correct?

3 A. Yes, sir.

4 Q. "But I'm going to include a note in the file to
12:13:51 5 watch this patient," correct?

6 A. Yes, sir.

7 Q. Okay. And it's always prudent if you have a little
8 bit of a concern, even if you feel "Just put a note in
9 the file to watch the patient," that's good pharmacy
12:14:04 10 practice, right?

11 A. Yes, sir.

12 Q. Okay.

13 A. And if I can just for clarification for the jury, I
14 think where they say minor emergency, it's not an age
12:14:12 15 consideration, it's minor as something that's not
16 serious.

17 So when you quoted the date of birth, I
18 just want to make sure the jury is aware.

19 Q. I think that's a great qualification, I think
12:14:23 20 you're absolutely right, so thank you.

21 I'm about to sit down. I just want to ask
22 you a few more questions, okay? But I want to be crystal
23 clear in asking these questions. Okay? Crystal clear.

24 We are not accusing NABP, your former
12:14:54 25 organization, or you, of any misconduct, okay? I want to

1 be crystal clear about that, and we'll tie it up at the
2 end to make that clear, okay?

3 Okay.

4 A. Sure.

12:15:04 5 Q. The stakeholder red flag project that you testified
6 about in response to questions from Walgreen's counsel,
7 you recall that, right?

8 A. Yes, sir.

9 Q. And that was a committee, it included Walgreen's,
12:15:20 10 correct?

11 A. A coalition.

12 Q. A coalition?

13 A. People get concerned when you say they served on a
14 committee, particularly when lawyers are around, so it
12:15:30 15 was a coalition.

16 Q. Coalition, and it included DEA, correct?

17 A. Yes, sir.

18 Q. It included doctors' associations, correct?

19 A. Yes, sir.

12:15:39 20 Q. It included my client, CVS, correct?

21 A. Yes, sir.

22 Q. It included your organization, NABP, correct?

23 A. Yes, sir.

24 Q. Okay. You interacted with my clients, correct?

12:15:47 25 A. Yes, sir.

1 Q. And it also included Purdue Pharma, correct?

2 A. Yes, sir.

3 Q. And that did not take away from the utility of the,
4 what do we call it, the stakeholders coalition at all,
12:16:02 5 correct?

6 A. In my opinion, no, sir.

7 Q. Okay. And I agree with you.

8 The NABP Foundation, you know that,
9 correct?

12:16:12 10 A. Yes, sir.

11 Q. That's the foundation that's affiliated with your
12 former organization NABP, correct?

13 A. Yes, sir.

14 Q. And you had involvement in the foundation, correct?

12:16:22 15 A. Yes, sir.

16 Q. Received a \$1 million grant from Purdue Pharma in
17 connection with NABP's efforts on the PDMP front,
18 correct?

19 A. Correct. I mentioned that last week to the jury.

12:16:36 20 Q. And that's the one, I believe, where you said you
21 sort of returned, you used that money to the communities
22 to try to help communities, correct?

23 A. Yes, sir. What we did is we published on the
24 foundation website the grant, and each amount of that
12:16:51 25 grant that was disbursed to the states for them to fund

1 their PMP to make enhancements so that people could
2 actually see where every dollar of that million dollars
3 went, and it went to the states.

12:17:08

4 Q. Okay. So NABP received the grant from Purdue and
5 NABP then disbursed it to the states for their use,
6 correct, for these very important reasons, correct?

7 A. Yes, sir.

8 Q. Okay. And NABP published an annual Survey of
9 Pharmacy Law, correct?

12:17:24

10 A. Yes, sir.

11 Q. And I'm showing you that, it's Defendant DEF MDL
12 1124.

13 A. I have that, sir.

12:17:41

14 Q. Okay. And this is an example of one of those
15 Surveys of Pharmacy Law that NABP sponsored, correct?

16 A. Yes, sir.

17 Q. Okay. And Purdue Pharma sponsored this publication
18 by NABP, correct?

12:18:00

19 A. What Purdue Pharma sponsored was us providing a
20 copy of the Survey of Pharmacy Law to every graduating
21 pharmacy senior.

22 Q. And that's a really good point.

23 This Survey of Pharmacy Law went to
24 graduating pharmacy students, correct?

12:18:12

25 A. Yes, sir.

1 Q. It went to future pharmacy -- future pharmacists?

2 A. Yes, sir.

3 Q. And the purpose of this was to give them, the
4 pharmacists, a resource that would help in their
12:18:25 5 understanding of the law, correct?

6 A. Yes, sir.

7 Q. Okay. And if we turn the page, there's -- well,
8 we'll look, first, at the second page of the document.

9 This is just the copyright page and it
12:18:39 10 contains -- I think your name is there, correct?

11 A. Yes, sir.

12 Q. Okay. Then we go to the third page of the
13 document, okay, and this is a letter from Purdue Pharma,
14 correct?

12:18:48 15 A. Yes, sir.

16 Q. And it's a letter from Kristi Dover, correct?

17 A. Yes, sir.

18 Q. And in her letter she says, "In your new career as
19 a pharmacist, your evaluation of the validity, safety and
12:19:02 20 appropriateness of prescriptions and medication orders
21 will be a critical aspect of health care delivery."

22 That's a correct statement, right?

23 A. Yes, sir.

24 Q. The letter goes on to say, "Purdue understands how
12:19:18 25 important it is for pharmacists to possess a strong

1 understanding of the rules and regulations governing the
2 practice of pharmacy."

3 Do you see that?

4 A. Yes, sir.

12:19:25 5 Q. And that's the letter that was included in NABP's,
6 your organization's Survey of Pharmacy Law that was
7 provided to pharmacy students, correct?

8 A. Yes, sir.

9 Q. Okay. And on the page that comes after the Purdue
12:19:40 10 letter is -- it's hard for me to get this on here because
11 I'm not particularly skilled with this, I think I told
12 the ladies and gentlemen of the jury that I'm really bad
13 with technology and even this technology I'm bad with.

14 This is a note from you, correct?

12:19:53 15 A. Yes, sir.

16 Q. And there's your signature at the bottom, correct?

17 A. Yes, sir.

18 Q. Okay. And Purdue's sponsorship of this publication
19 did not detract from it in any way whatsoever, correct?

12:20:07 20 A. Correct, sir.

21 Q. Okay. The Purdue executive or the Purdue employee
22 who signed this is a person named Kristi Dover, correct?

23 A. Yes, sir.

24 Q. And you know Kristi Dover, correct?

12:20:17 25 A. Correct.

1 Q. As a matter of fact, you asked Ms. Dover to serve
2 on an NABP task force aimed at looking at the Controlled
3 Substances Act, the Controlled Substances Act, and
4 determining whether it should be revised in any ways,
12:20:32 5 correct?

6 A. Yes, sir.

7 Q. Okay. And NABP gave a very prestigious award to
8 Ms. Dover for her service, correct?

9 A. Correct.

12:20:40 10 Q. The award was the Henry Cade Memorial Award,
11 correct?

12 A. Correct.

13 Q. And NABP gave Ms. Dover that award while she was at
14 Purdue Pharma, correct?

12:20:52 15 A. Correct.

16 Q. Okay. Now, here's the punch line that I promised
17 would be coming.

18 None of this, none of your interactions or
19 NABP's interactions with Purdue involved any misconduct
12:21:06 20 by Purdue, correct?

21 That was a terrible -- I'll withdraw it.

22 A. You mind if I can answer it?

23 THE COURT: Hold it, Doctor. Mr. Delinsky
24 withdrew his question so he needs to pose another one.

12:21:31 25 THE WITNESS: Okay.

1 MR. DELINSKY: Sometimes they just come out
2 really terribly.

3 BY MR. DELINSKY:

4 Q. By working with Purdue on these projects, accepting
12:21:37 5 their money, their sponsorship, working with people like
6 Ms. Dover, neither you nor your organization NABP
7 participated in any misconduct whatsoever that Purdue may
8 or may not have been involved in, correct?

9 A. Correct, sir.

12:21:52 10 Q. Okay.

11 MR. DELINSKY: Thank you very much,
12 Mr. Catizone. I appreciate it.

13 Thank you, ladies and gentlemen, Your
14 Honor.

12:22:02 15 THE COURT: Okay. Ladies and gentlemen,
16 before we do the redirect, if any of the jurors have any
17 questions, you should hand them to Mr. Pitts, and I will
18 give them to both counsel.

19 (Pause.)

12:22:51 20 THE COURT: Okay. I guess, Mr. Lanier, you
21 can begin.

22 MR. LANIER: Thank you. Thank you, Judge.

23 REDIRECT EXAMINATION OF CARMEN CATIZONE

24 BY MR. LANIER:

12:23:26 25 Q. Mr. Catizone.

1 A. Yes, sir.

2 Q. It's been awhile.

3 A. Yes, sir.

4 Q. So I want to ask you about things that you were

12:23:35 5 cross-examined on Friday -- no, yes, it was Friday -- as

6 well as today.

7 I've tried to put together a roadmap to

8 give you an idea, call it "Redirect Road," because I'm

9 going to redirect the examination.

12:23:50 10 You follow me?

11 A. Yes, sir.

12 Q. Now, I originally had four stops -- we were going

13 to talk about red flags, documentation, policies and then

14 the NABP -- but I decided to put a detour on here with

12:24:03 15 some questions that were asked by Ms. Sullivan concerning

16 the AMA.

17 So we'll start actually with the detour,

18 okay?

19 A. Yes, sir.

12:24:11 20 Q. You were asked these questions, you were asked

21 these questions this morning, and one of the issues that

22 you were asked about was Defendants' Exhibit 35922. And

23 the way this was being read to you and the jury was that

24 "Our AMA deem inappropriate inquiries from pharmacies to

12:24:47 25 verify the medical rationale behind prescriptions,

1 diagnoses and treatment plans to be an interference with
2 the practice of medicine and unwarranted."

3 I believe even the Court noted that that
4 seems to be poor grammatically. Do you remember those
12:25:02 5 questions?

6 A. Yes, sir.

7 Q. Well, if instead of putting the emphasis the way
8 Ms. Sullivan did, we just read it, "Our AMA" --

9 MS. SULLIVAN: Objection, Your Honor.

12:25:14 10 That's argument.

11 I did just read it.

12 MR. LANIER: No.

13 THE COURT: All right.

14 MR. LANIER: I'll reask it this way.

12:25:19 15 THE COURT: You can rephrase it.

16 I'll sustain the objection the way it was
17 asked.

18 BY MR. LANIER:

19 Q. Okay. See if it makes sense to read it like this,
12:25:27 20 that "Our AMA deem inappropriate inquiries from

21 pharmacies to verify the medical rationale behind
22 prescriptions, diagnoses and treatment plans to be an
23 interference with the practice of medicine and
24 unwarranted," do you see a difference in those two?

12:25:45 25 A. Yes, sir.

1 Q. Aside from the fact of whether the AMA is even most
2 doctors, do you see how this speaks to inappropriate
3 inquiries as a wrongful intrusion?

4 A. Yes.

12:26:03 5 Q. Is that consistent with your MRI comment?

6 A. Yes, it is.

7 Q. Is it consistent with your memory of the
8 stakeholders meeting?

9 A. Yes, it is, sir.

12:26:13 10 Q. Is it consistent with your dialogue with the
11 various doctors involved?

12 A. Yes, sir.

13 Q. And so what do you believe it to mean to you as a
14 pharmacist and a man who is involved in this work that
12:26:29 15 the AMA deem inappropriate inquiries from pharmacists to
16 be an interference?

17 MS. SULLIVAN: Objection.

18 BY MR. LANIER:

19 Q. What would be an inappropriate inquiry?

12:26:40 20 MS. SULLIVAN: I'm sorry, Mr. Lanier.

21 Objection, Your Honor. No foundation he
22 had anything to do with the resolution by the AMA.

23 MR. LANIER: Your Honor --

24 THE COURT: Well, I'm going to sustain it
12:26:53 25 the way you asked it.

1 BY MR. LANIER:

2 Q. All right. In terms of the dialogues that you've
3 had -- no, I'll take that back, too.

4 Let me ask it this way.

12:27:04 5 Sir, just as a pharmacist, what would you
6 consider to be an inappropriate inquiry from a pharmacy?

7 A. Based on my experience as a pharmacist and what
8 transpired at the time that I witnessed, some pharmacists
9 were requesting things like MRIs or very extensive
12:27:23 10 diagnosis information that went beyond the scope of what
11 a pharmacist should ask.

12 And pharmacy groups that I spoke with
13 acknowledged that as well, that there was blame on both
14 sides; that the doctors have to recognize the role of the
12:27:38 15 pharmacists and pharmacists have to recognize the role of
16 the doctors, and neither side can go too far and
17 interfere with what the prescribers need to do and what
18 the pharmacists need to do.

19 MS. SULLIVAN: Objection, Your Honor.
12:27:50 20 Move to strike on hearsay grounds.

21 THE COURT: Overruled.

22 BY MR. LANIER:

23 Q. If it's been suggested to the jury through the
24 questioning of you by Ms. Sullivan, Giant Eagle's lawyer,
12:27:59 25 if it's been suggested that the AMA was saying there

1 should be no questions by pharmacists of doctors, would
2 you agree with that?

3 MS. SULLIVAN: Objection, Your Honor.

4 That was not my question. Mischaracterized
12:28:14 5 it. It's argument.

6 THE COURT: I'll overrule it.

7 He said if it was, if it was your question.
8 If it was, the jury is to remember what the question and
9 answer was.

12:28:27 10 A. No, sir, I don't agree with that.

11 BY MR. LANIER:

12 Q. All right. By the way, if some doctors are getting
13 annoyed if pharmacists second-guess them, does that
14 matter?

12:28:42 15 A. Not if the patient comes first and if the
16 pharmacist is doing what they're supposed to do.

17 Q. Should the pharmacists do the right thing even if
18 it annoys some doctors?

19 A. Yes.

12:28:53 20 Q. Okay. Now, that's the detour. Let's get to the
21 red flags and then the documentation.

22 You were asked a number of questions about
23 red flags, and I'd like to try and go through them,
24 recognizing that some were last Friday and some were this
12:29:25 25 morning. All right?

1 A. Yes, sir.

2 Q. First of all, this morning you were asked about
3 your red flags or the red flags you came up with in this
4 litigation, or the red flags that you created for this
12:29:40 5 litigation.

6 Walgreen's lawyer over and over asked that.

7 My question to you, sir, is did you make up
8 these red flags?

9 A. No, sir. They came from DEA documents, they came
12:29:52 10 from DEA decisions in administrative cases and criminal
11 and civil cases, and they are information that was known
12 or should be known to all pharmacists.

13 Q. Should Walgreen's know that these aren't made up by
14 you?

12:30:04 15 A. I -- I would hope so, sir.

16 Q. I mean, shouldn't -- shouldn't the chain pharmacies
17 certainly understand what red flags are?

18 A. There's been enough documentation, presentations by
19 the DEA and state Boards of Pharmacy, that that
12:30:20 20 information should have been known.

21 Q. In fact, are there more red flags than those you
22 selected for us here?

23 A. Yes, sir.

24 Q. Now, general red flag questions.

12:30:35 25 Can red flags be resolved?

1 A. Except for the one that we discussed, the trinity,
2 the holy trinity, yes, they can be resolved, sir.

3 Q. But why do pharmacists have to be so careful to
4 resolve them?

12:30:53 5 A. Every time a pharmacist dispenses a prescription,
6 on the other side of that prescription is a patient or a
7 family member of that patient.

8 If the pharmacist doesn't take care in
9 dispensing that prescription and resolving that red flag,
12:31:08 10 two things happen.

11 One, that prescription gets to the patient
12 and could injure the patient.

13 Second is the controlled and closed system
14 that we've talked about that's been established by the
12:31:24 15 federal laws and such, that closed system is breached.

16 And now medications that should have been dispensed to
17 the patient for a legitimate medical purpose get outside
18 of that system to be abused, to be diverted, and now
19 we're talking about patients who are really at risk now
12:31:45 20 or individuals who are really at risk because that
21 medication has left that closed system and is being
22 abused and diverted.

23 Q. Okay. Well, why is it important that pharmacists
24 document this resolution?

12:31:58 25 A. Again, as we went through some of the notes and

1 some of the examples, as a pharmacist filling that
2 prescription after the initial fill or after the refills,
3 if I don't understand what happened with that patient or
4 that the red flags were resolved, I'm going to ask the
5 same questions of the patient or perhaps I'm not going to
6 dispense it, and the patient's going to be denied their
7 medication.

8 So documentation is key for me and everyone
9 else looking at that to keep the patient safe and know
10 that that system is still closed and that those red flags
11 have been resolved.

12 Q. All right. You were asked by the lawyer for
13 Walgreen's about your familiarity with Lake and Trumbull
14 County.

15 Remember those questions?

16 A. Yes, sir.

17 Q. I think they wanted to know what are the major
18 towns, you know, that kind of stuff.

19 Remember?

20 A. Yes, sir.

21 Q. Here's my question. Can you think of any reason
22 that Walgreen's shouldn't protect those citizens just as
23 much as the citizens of Cleveland?

24 MR. SWANSON: Objection, Your Honor.

25 This is just argument.

1 MR. LANIER: It's a direct reply, Judge, to
2 his questions about familiarity.

3 Let me ask it this way.

4 THE COURT: I'm going to sustain, sustain
5 it the way you've asked that.

6 BY MR. LANIER:

7 Q. All right. Let me ask it this way.

8 Does geography change the rules of the DEA?

9 A. No, sir.

10 Q. Do you have any reason to suspect that two counties
11 in Northeast Ohio are exempt from the rules?

12 A. No, sir.

13 Q. Do you have any reason to suspect that two counties
14 from Northeast Ohio should not have the same protections
15 as everybody else?

16 A. No, sir.

17 Quite the opposite. Every individual in
18 the country, every county, should have the same
19 protections and the same requirements.

20 Q. So the steps that a pharmacist should take when
21 faced with red flags, does it change when all of a sudden
22 you go to Trumbull County?

23 A. No, sir.

24 Q. Well --

25 A. They're universal. They apply across all patients,

1 all geographic locations, all settings.

2 Q. Is it ever right in any location to take shortcuts
3 when you're dispensing opioids?

4 A. No, sir.

12:34:16 5 Q. Even if you think that you're a smaller county
6 where there are only 200,000 people and you know a good
7 bit of them, does that allow it?

8 A. Those shortcuts put patients at risk and the
9 pharmacist is not meeting the responsibility, so the
12:34:29 10 answer is no, sir.

11 Q. Now, you were also asked about your eyeballs that
12 were on prescriptions and what those prescriptions
13 actually said and did.

14 Do you remember that?

12:34:44 15 A. Yes, sir.

16 Q. And then you were asked about files of refusals to
17 fill.

18 Do you remember those questions?

19 A. Yes, sir.

12:34:53 20 Q. Do you expect every bad prescription to be filled?

21 A. Yes -- no.

22 Q. Let's do that one again.

23 Do you expect -- let me ask it, I will ask
24 a clearer question.

12:35:12 25 Do you know anybody who's arguing that the

1 pharmacies never did their job right?

2 A. No, sir.

3 Q. Of course they did their job right many times,
4 would you agree?

12:35:23 5 A. Yes, sir.

6 Q. Okay. Would you agree that not every prescription
7 is a bad prescription?

8 A. Yes.

9 MR. SWANSON: Your Honor, can I get an
12:35:31 10 objection on this? It's just leading, showing him
11 statements that --

12 THE COURT: Hold.

13 I'm going to sustain. Mr. Lanier, I have
14 no problem with your showing the question before you ask
12:35:41 15 it. I do have a problem with you showing him an answer
16 or a possible --

17 MR. LANIER: You're exactly right, Your
18 Honor, and I apologize.

19 THE COURT: The objection will be
12:35:50 20 sustained.

21 MR. LANIER: You're exactly right, I
22 apologize.

23 BY MR. LANIER:

24 Q. But look at Plaintiffs' Exhibit 17230, which is one
12:35:56 25 that was turned away.

1 Do you remember this?

2 A. Yes, sir.

3 Q. Where did this prescription come from?

4 A. The Cleveland Clinic, sir.

12:36:08 5 Q. So in spite of everything that we've heard that you
6 never need to check on a Cleveland Clinic prescription,
7 would you agree that sometimes even the Cleveland Clinic
8 might give a prescription that should be turned away?

9 MR. SWANSON: Objection. Objection, Your
12:36:23 10 Honor. That's not what anybody has said.

11 THE COURT: Well, I'll overrule it.

12 He can answer. Answer and ask the
13 question -- or ask and answer the question.

14 A. Yes. One of the examples we talked about were the
12:36:36 15 assumption that people make, just because it's the
16 Cleveland Clinic, that everything is appropriate there.

17 And I think I commented where the question
18 was asked that I've seen fraudulent or illegitimate
19 prescriptions from the Cleveland Clinic, Massachusetts
12:36:49 20 General, the Mayo Clinic.

21 So just because it comes from the Cleveland
22 Clinic doesn't mean that you avoid doing all the due
23 diligence and red flag work that you need to do.

24 Q. And as for this whole category of documents where
12:37:02 25 the pharmacies did refuse to fill, did we ask you to

1 analyze whether or not those were done properly?

2 A. No, sir, but here's the problem I have with that.

3 Each of the defendants provided a
4 representative sample of their prescriptions.

12:37:22 5 So just talking common sense and logic,
6 there should have been some of those do not fill
7 prescriptions that were just shown in that sample,
8 because if you take a random sample and you have enough
9 of those, that they're going to be represented, some of
12:37:41 10 them should have come up to the surface or should have
11 been in the sample.

12 I didn't see any of those in the
13 prescriptions I reviewed, which from a logic standpoint
14 says either there were so few of those that when you do a
12:37:55 15 random study, a random selection, they don't appear; or
16 for some other reason, which I can't come up with another
17 reason, just bad draw, that none of those prescriptions
18 presented.

19 But a representative sample is just that,
12:38:09 20 it gives you a snapshot of that entire sample of
21 prescriptions. And why none of those came up in the
22 sample is -- is a -- it's confusing to me, if there was
23 that many or if there were actually prescriptions being
24 turned away at the numbers as may be suggested.

12:38:26 25 Q. All right. If we go back to last Friday, out of

1 the 1,800 Walmart prescriptions, I want you to look at
2 the one that they chose first to talk to you about and
3 ask you this question.

4 Why aren't the red flags resolved?

12:38:41 5 Here's the prescription, it's marked
6 Walmart MDL 13343_0241.

7 Can you see that well enough to tell us why
8 the red flags were not resolved?

9 A. So the red flag, the notation says they're aware of
12:39:07 10 the script on one, I believe, 20, 29, and I can't make
11 out what that is. "Okay to fill per doctor, 6:30."

12 And then the documentation there, based
13 upon the red flags that were noted with this
14 prescription, doesn't explain it thoroughly, doesn't
12:39:28 15 document it thoroughly.

16 Q. And then with the same number you were shown the
17 hospice patient prescription.

18 Do you remember that?

19 A. Yes.

12:39:38 20 Q. And my question to you on that one is why is it
21 important to resolve red flags even if it's a hospice
22 patient?

23 A. Again, with all of the prescriptions that we're
24 looking at, it wasn't just the one red flag, sir, there
12:39:57 25 were multiple red flags.

1 With some of the patients it may be the
2 distance, where they traveled from out of state and came
3 to the pharmacy. So until those red flags were resolved,
4 then you really can't move forward with the prescription.

12:40:09 5 If you look at the patient we talked about
6 on Friday, I believe she was in her 70s, suffering from
7 lung cancer, and we get an opioid and a Benzodiazepine, I
8 think that's what the prescription was.

9 So we've got a poor individual who is
12:40:26 10 suffering so bad from lung cancer that she can't even
11 breathe, and so they give her a medication to help her
12 breathing. But they've also given her a Benzodiazepine,
13 so as a pharmacist now I'm worried about that patient
14 because the opioid and the Benzodiazepine slow or can
12:40:46 15 stop that breathing.

16 So I've got a woman already compromised and
17 I have to be very careful to make sure I don't give her
18 too much of that medication to actually stop her
19 breathing and really injure that poor patient.

12:41:03 20 Q. All right. As we continue through this stop of the
21 red flags, you were asked this morning about the DEA
22 speaking of trinity cocktails being okay.

23 Do you remember those questions?

24 A. Yes, sir.

12:41:17 25 Q. You had the document there in front of you from the

1 DEA.

2 Does the DEA in that document actually say
3 it's okay to prescribe the holy trinity?

12:41:37

4 A. As we discussed earlier, the DEA can only comment
5 on where it has jurisdiction over and it only has
6 jurisdiction over the Controlled Substances Act.

7 It can't talk about anything outside of
8 that because they have no authority or no reason to be
9 involved in that.

12:41:49

10 The letter prior to that that elicited this
11 response specifically asked can we dispense the trinity
12 or is it inappropriate or prohibited to dispense the holy
13 trinity, and nowhere in this letter does the DEA answer
14 that very direct question by saying, "Yes, it's okay" or
15 "No, it's okay."

12:42:12

16 They simply said, which is what the DEA can
17 only say, that you have to practice according to what
18 your professional standards and laws allow, and only can
19 comment on is the Controlled Substances Act says that we
20 can't tell you what to do or not to do in regard to
21 Medical Board issues or standard of care issues involving
22 patient care.

12:42:26

23 Q. And in that regard, you pointed out to the lawyer
24 asking questions and the jury this second paragraph, "The
25 DEA may only address its position based on the authority

12:42:46

1 granted by the Controlled Substances Act and its
2 implementing regulations."

3 The DEA's longstanding policy is not to
4 provide legal advice to private parties, and so they give
12:43:01 5 the following general information.

6 What is your understanding of this response
7 from the DOJ, Department of Justice?

8 A. My understanding is that this is very typical of
9 every federal agency, DEA, FDA.

12:43:18 10 They cannot go beyond what's written in the
11 law and what they've sent out as guidance documents. To
12 go beyond that would put them in a very difficult
13 position and probably they would be acting illegally to
14 give any opinions or advice outside of what that law says
12:43:35 15 or what guidance documents they've provided.

16 Q. All right. In this regard, you were asked about
17 the pharmacy manual in 2020 when the opioid crisis was in
18 full bloom, as Ms. Sullivan, the Giant Eagle lawyer,
19 said, and my question to you is this: That out of scope
12:43:59 20 section on Page 114, is that an exclusive list of red
21 flags?

22 And I'll show you Page 114 so you can
23 answer it. This is the section that Ms. Sullivan was
24 quizzing you about.

12:44:17 25 A. No.

1 Q. It says --

2 A. It's not an exclusive list, and you can even see by
3 the language, it says "The following criteria may
4 indicate." It doesn't say this is the definitive list of
5 criteria, and there are no more.

12:44:28

6 And if you read the entire *Pharmacist's*
7 *Manual*, there are references throughout that to other DEA
8 cases, other DEA decisions or guidance that provide
9 information and identify other red flags as well.

12:44:44

10 Q. And by the same token, you were shown earlier the
11 National Association of Boards of Pharmacy, your NABP,
12 and the stakeholders meeting with the AMA and the
13 pharmacies.

14 Remember that?

12:44:58

15 A. Yes, sir.

16 Q. A document that I'd like to show you at this point
17 in time, which is Plaintiffs' Exhibit 26403, Plaintiffs'
18 Exhibit 26403 is a document that's a follow-up to that
19 meeting, "Follow-up stakeholder meeting on prescribing
20 and dispensing controlled substances" with a Stakeholder
21 Meeting Booklet PDF attached.

12:45:39

22 Do you see that?

23 A. Yes, sir.

24 Q. And it's got a CC to you, so you are one of the
25 people who received this.

12:45:51

1 Is that fair?

2 A. Yes, sir.

3 Q. And it is sent from Dana Oberman.

4 Is she one of the folks that worked with
12:45:59 5 you at the NABP?

6 A. Yes, sir.

7 Q. And it's sent to a number of people. The jury will
8 meet many of these. They've already met at least one of
9 them from CVS, I believe that gentleman is on here, but
12:46:13 10 we've got Walgreen's, we've got the AMA gentleman, and I
11 may be wrong on the CVS. I may have misread it.

12 But let's stick with Walgreen's. Clearly
13 the Walgreen's people who were quizzing you are on here,
14 is that correct?

12:46:30 15 A. Not the person who asked questions today, but other
16 Walgreen's people. Thank you.

17 Q. All right. And there he is, Mr. Davis, the first
18 witness.

19 Okay. In regards to this document that's
12:46:43 20 dated back in 2013, does it already talk about red flags
21 in 2013?

22 A. Yes, it does.

23 Q. And if you'll look, you will see that it's not only
24 an editing of documents, but that it's got a PowerPoint
12:46:59 25 attached.

1 The PowerPoint begins on Page, Bates Number
2 Page 49.

3 The PowerPoint's entitled, "The evolving
4 concept of corresponding responsibility."

12:47:22 5 Do you see that?

6 A. Yes, sir.

7 Q. I'd ask you to flip a couple of pages to the back,
8 and let's kind of work from the back forward with this
9 document.

12:47:33 10 And so if you'll go, please, to Page 77 of
11 the PowerPoint, you'll see one entitled "Red flags."

12 Do you see that?

13 A. Yes, sir.

14 Q. Okay. These red flags are going on for pages.

12:47:55 15 That's the last page, but there were red
16 flags in the page before, red flags in the page before,
17 red flags in the page before, red flags in the page
18 before, red flags in the page before, red flags in the
19 page before.

12:48:15 20 Do you see that?

21 A. Yes, sir.

22 Q. To suggest that you made up or created red flags
23 for purposes of this case, is that a fair representation
24 of what you've done?

12:48:27 25 A. No, sir.

1 Q. Did these red flags already exist for some time?

2 A. Yes, sir.

3 And the slide presentation was done by an
4 outside law firm that NABP has no affiliation or
12:48:42 5 contracts with, Quarles & Brady, so it wasn't even an
6 NABP-prepared document.

7 It was something that this law firm has
8 given presentations on and speaks to pharmacies and
9 pharmacists about as well.

12:48:53 10 Q. In that regard, if we continue to look at what was
11 presented and sent around to at least Walgreen's and CVS,
12 if you'll look on Slide 56, it goes back to 1989.

13 Do you see that?

14 A. Yes, sir.

12:49:13 15 Q. And in 1989, it notes something about Ralph J.
16 Bertolino.

17 Do you know about that?

18 A. Vaguely I remember that, sir.

19 Q. "Facts supporting failure to exercise corresponding
12:49:30 20 responsibility.

21 "The number of prescriptions issued by a
22 small number of prescribers, the number of dosage units,
23 the duration and pattern of the alleged treatment," and
24 it looks like it's specifically talking in that case
12:49:43 25 about the drug Preludin as a widely abused drug.

1 Do you see that?

2 A. Yes, sir.

3 Q. I don't think Preludin is an opioid, is it?

4 A. No, sir.

12:49:54 5 Q. But the idea of corresponding responsibility is the
6 same -- is it the same idea?

7 A. Yes, sir. There's another point here as well, so
8 there's been some question about red flags and whether
9 red flags have been specifically mentioned in various
12:50:09 10 documents or regulations.

11 The concept of red flags as warning signs
12 has existed for 40, 50 years, as you can see by this
13 document.

14 So whether it's called the red flag, the
12:50:23 15 warning sign, a criteria, indicator, it hasn't changed.
16 It's only increased based upon new information, so
17 pharmacists have been advised of red flags for a long,
18 long time.

19 Whether or not they are specifically called
12:50:35 20 red flags, they're warning signs. And warning signs have
21 been known for quite awhile.

22 Q. If we continue to look at this PowerPoint that was
23 sent out with the stakeholders meeting, it has another
24 one from 1989, Liberty Discount Drugs on Page 57, where
12:50:56 25 it talks about a dispensing pattern being indicative of

1 diversion even for those with no pharmacy training.

2 Can you comment on whether or not that red
3 flag still exists today?

4 A. It still exists, and it's an example of what we
12:51:17 5 talked about the past couple days.

6 The regulations spell out what should be
7 required, and then DEA actions like the Liberty and
8 Bertolino provide more clarity and identify very specific
9 incidents or very specific red flags pertaining to that
12:51:32 10 overall general requirement.

11 Q. And then the next bullet point, this idea that
12 pharmacists can say not my job to detect because
13 customers have a right to get prescriptions filled, has
14 that excuse been known since 1989?

12:51:52 15 A. Yes, it has.

16 Q. And is it an acceptable excuse?

17 A. It was not acceptable in 1989 and it's not
18 acceptable in 2021, and it won't be acceptable in 2089.

19 Q. And if we continue to go further, if we come up to
12:52:10 20 2008 and the reference in 2008 to the *Med. Shoppe versus*
21 *DEA* matter, do you have that?

22 A. Yes, sir.

23 Q. Slide 62?

24 A. Yes, sir.

12:52:19 25 Q. It talks about "Facts proving pharmacist did not

1 fulfill corresponding responsibility," and one of them is
2 "Drugs prescribed by practitioner outside the normal
3 practice area."

4 Is that one of your red flags?

12:52:35 5 A. Yes, it is.

6 Q. Did you make it up?

7 A. No, sir.

8 All the red flags I included in my report
9 and asked for analysis on have come from these types of
10 documents, these types of guidance from the DEA.

11 Q. Evidence that patients were doctor-shopping, is
12 that still a red flag?

13 A. Yes, it is.

14 Q. Did you make that one up?

12:52:56 15 A. No, sir.

16 Q. If we continue and you look at the next page,
17 Page 63, you'll see that this document even uses the
18 language "Red flag" in reference to the *Holiday* case.

19 Are you familiar with the *Holiday CVS*
12:53:16 20 action?

21 A. Yes, I am.

22 Q. 2012?

23 A. Yes, I am, sir.

24 MR. DELINSKY: Objection, Your Honor.

12:53:23 25 THE COURT: Overruled.

1 BY MR. LANIER:

2 Q. Are you familiar with it, sir?

3 A. Yes, sir.

12:53:30

4 Q. This comment on the slide that was part of your
5 stakeholders send-out, "Violation of corresponding
6 responsibility required delivery of controlled substance,
7 a red flag was or should have been recognized, the
8 question raised by the red flag was not resolved
9 conclusively prior to dispensing."

12:53:48

10 Is that a red flag still today?

11 A. Yes, it is.

12 Q. And these red flags, were they known back in 2012?

13 A. Yes, sir, they were.

12:54:07

14 Q. Did y'all mail this out as part of your
15 stakeholders summation?

16 A. Yes, we did.

17 Q. If we continue to look at what y'all mailed out to
18 people, you've got, on Page 64, this section from *Holiday*
19 that says the irresolvable red flags.

12:54:31

20 MR. DELINSKY: Same objection, Your Honor.

21 THE COURT: Well, yeah, I'm going to
22 sustain this.

12:54:47

23 MR. LANIER: Okay. Well, my question was
24 whether or not these are irresolvable red flags, in his
25 mind today. I just hadn't gotten the question out.

1 THE COURT: Well, I'm going to sustain this
2 slide.

3 MR. LANIER: Okay.

4 BY MR. LANIER:

12:54:56 5 Q. If we continue to look at --

6 MR. LANIER: Your Honor, I don't mean to be
7 persistent, it's the next slide that I was going to use
8 from that that talks about irresolvable red flags from
9 *Holiday*.

12:55:17 10 THE COURT: All right. The *Holiday* you can
11 put up.

12 MR. LANIER: Thank you, Judge.

13 BY MR. LANIER:

14 Q. The irresolvable red flags of dispensing Oxycodone
12:55:24 15 30 and 15 to the same patient, is that still a red flag
16 in your book today?

17 A. It's -- it's a red flag still.

18 Q. Prescribers whose prescribing pattern suggests a
19 one size fits all concept, is that one of your red flags?

12:55:40 20 A. One of the ones I've asked to be analyzed, yes,
21 sir.

22 Q. Okay. Did you make that up?

23 A. No, sir.

24 Q. Sir, the red flags that you've testified about in
12:55:59 25 this case, why are they important?

1 A. As we talked earlier, if controlled substances,
2 particularly opioids, get outside of that closed system
3 that's so safely guarded by all the laws, regulations,
4 and the pharmacists' responsibility, those products
12:56:17 5 are -- can be abused and diverted. And when they're
6 abused and diverted, that's what we see happening in all
7 of our -- across the country with the opioid epidemic.

8 Q. All right. Then let's move from red flags to
9 documentation.

12:56:39 10 The documentation questions that you were
11 asked from last week and this week, I've tried to put
12 together, but I want to start by saying that the data set
13 you looked at, those 7,800 prescriptions, right?

14 A. Yes, sir.

12:56:57 15 Q. You understand that those are from a set that
16 admittedly were filled?

17 A. Yes, sir.

18 Q. So this is not one where you don't know if it was
19 filled or not, because they've been represented by the
12:57:11 20 defendants as being filled.

21 Do you understand?

22 A. Yes, sir.

23 Q. Okay. So why is documentation so important when it
24 comes to opioids?

12:57:20 25 A. As we've talked about, the documentation provides

1 information for pharmacists or others looking at that
2 prescription afterwards. It documents that there was a
3 legitimate medical need for that prescription and it
4 helps resolve any red flags that may prevent the patient
12:57:37 5 from having access to the medications they need.

6 Q. All right. Now, in that regard, you were asked
7 questions by the lawyer for Walmart, I believe went
8 first, and in it she put forward the *Pharmacist's Manual*
9 from 2020, which is marked as Defendants' Exhibit 11599.

12:58:05 10 Do you remember this?

11 A. Yes, sir.

12 Q. And it's an informational outline of the Controlled
13 Substances Act.

14 Now, she asked you a question, and you gave
12:58:16 15 an answer.

16 She said, "In this DEA *Pharmacist's Manual*,
17 it doesn't say anywhere that a pharmacist should document
18 the resolution of red flags, correct?"

19 Your answer was: "I would like the
12:58:30 20 opportunity to go through and see that for myself to make
21 that statement."

22 Do you remember that answer?

23 A. Yes, sir.

24 Q. In that regard, I'd like to show you Page 35 and
12:58:41 25 ask you if this has any relevance at all to this subject.

1 A. That's the reference I spoke about earlier,
2 probably on Thursday.

3 That's the specific reference to
4 documentation that forms the basis for the opinions I
12:58:55 5 presented.

6 Q. So this being in that document that she
7 said -- asked you the question about, it reads -- why
8 don't you read it for the jury and explain it?

9 A. Sure.

12:59:06 10 "Every pharmacy must maintain complete and
11 accurate records on a current basis for each controlled
12 substance received, sold, delivered, or otherwise
13 disposed of."

14 Yes, the word "Document" may not be present
12:59:24 15 in the *Pharmacist's Manual*, but clearly if you say
16 "maintain complete and accurate records," I don't know
17 how else you would define "Document."

18 Q. And it says, "These records are required to prove
19 accountability of all controlled substances from the
12:59:45 20 manufacturing process through the dispensing pharmacy and
21 to the ultimate user."

22 Why is -- why are records like you're
23 talking about required to provide accountability?

24 A. The reason is the next sentence. "The closed
13:00:03 25 system reduces the potential for diversion of controlled

1 substances."

2 Without that closed system, without that
3 documentation, opioids get outside of the pharmacy and
4 the patient, into the hands of people then that abuse and
13:00:17 5 divert those drugs, and that causes serious harm and
6 death.

7 MR. LANIER: Your Honor, I know you've got
8 a commitment.

9 It is 1:00 o'clock, and I don't want to
13:00:25 10 abuse that.

11 THE COURT: I was going to suggest it, if
12 you've finished with this document it's a good time to
13 break.

14 MR. LANIER: Yes, Your Honor.

13:00:32 15 THE COURT: All right. Thank you, ladies
16 and gentlemen, for indulging my schedule.

17 We'll take our lunch break. Because you've
18 gone longer we'll go until 2:15, and then we'll pick up
19 with the balance of Dr. Catizone's testimony.

13:00:49 20 (Jury out.)

21 THE COURT: Be seated for a second.

22 I did understand the next witness is
23 Mr. Rannazzisi. I've read the defendants' objections,
24 motion in limine, and the plaintiffs' response.

13:01:44 25 All I'll say is this: The plaintiffs have

1 agreed they're calling Mr. Rannazzisi as a fact witness.
2 Therefore, he's not going to give any expert testimony.

3 And as a fact witness, I intend to apply
4 the rules that apply to all fact witnesses, which he
13:02:03 5 can't -- he can only testify to matters, statements,
6 whatever, within his personal, personal knowledge and
7 experience.

8 So if there are objections based on hearsay
9 or outside his personal knowledge, defendants can object,
13:02:20 10 and I'll have to rule on them on a question-by-question
11 basis.

12 MR. LANIER: One thing that will help me
13 frame my questions is a number of the *Touhy*
14 authorizations that have been granted by the Government
13:02:35 15 say that he is allowed to say, since he was the head of
16 the DEA for this stuff, he's allowed to say this was the
17 DEA position.

18 I don't think that's an expert opinion.

19 THE COURT: Well --

13:02:46 20 MR. LANIER: As long as it was his position
21 at the time.

22 THE COURT: Right. He can testify since he
23 was a DEA official, he can testify to his understanding
24 of what the DEA's position was at that time.

13:02:56 25 MR. LANIER: Thank you.

1 MR. MAJORAS: Your Honor, John Majoras.

2 Certainly we will object as necessary, but
3 to give a broad license to talk about everything in the
4 DEA given his specific role in the DEA would certainly be
13:03:09 5 going too far.

6 MR. LANIER: And I won't do that. It's
7 within his personal knowledge of the job he was doing.

8 THE COURT: Right. Absolutely.

9 Okay. Thank you.

13:03:17 10 Have a good lunch.

11 MR. LANIER: Thank you, Judge.

12 (Luncheon recess taken).

13 (Proceedings concluded at 1:04 p.m.)

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1 TUESDAY, OCTOBER 12, 2021, 2:17 P.M.

2 (Jury in.)

3 THE COURT: Okay. Please be seated.

4 Mr. Lanier, you may continue. And,

14:19:12 5 Dr. Catizone, you are still under oath.

6 MR. LANIER: Thank you, Your Honor. May it
7 please the Court, ladies and gentlemen, good afternoon.

8 REDIRECT EXAMINATION OF CARMEN CATIZONE (RESUMED)

9 BY MR. LANIER:

14:19:19 10 Q. Mr. Catizone, we were at documentation station, for
11 lack of a better way of saying it, all right?

12 A. Yes, sir.

13 Q. And in that regard, I want to ask you a couple of
14 questions about documentation covering what's already
14:19:30 15 been asked of you.

16 First of all, you were asked questions
17 about the importance of documenting.

18 You got that asked by all of the lawyers on
19 the other side.

14:19:40 20 Do you remember that?

21 A. Yes, sir.

22 Q. All right. Here are my questions in response.

23 Should corporate policies ensure
24 documentation?

14:19:49 25 A. Yes, they should.

1 Q. Even if it takes time to do the documenting?

2 A. Yes, sir.

3 Q. Should it diminish one's bonus to have to document
4 and to take that time?

14:20:05 5 A. No, sir.

6 Q. Now, you were asked questions about prior notes.

7 Do you remember those questions?

8 A. Yes, sir.

9 Q. In other words, you had the 2,000 per defendant
14:20:38 10 save, I think, 1,800 for Walmart, but you had those that
11 you actually looked at the dispensing notes on.

12 Remember?

13 A. Yes, sir.

14 Q. Okay. And then you were asked questions this
14:20:48 15 morning about, well, did you ever go back and look at the
16 hundreds of thousands of other notes that were there.

17 Remember?

18 A. Yes, sir.

19 Q. All right. And we've pulled some of those, if
14:21:01 20 we've got time to look at them.

21 But regardless of that, let me ask you
22 this: If red flags get resolved by looking back through
23 hundreds of thousands of prescriptions to find a note
24 that resolves the red flag, should the pharmacist
14:21:19 25 document that?

1 MS. SULLIVAN: Objection, Your Honor.

2 That's argument.

3 THE COURT: Yeah, I'm going to sustain
4 that.

14:21:25 5 BY MR. LANIER:

6 Q. Okay. Should, if the pharmacist goes through the
7 prior notes and finds something that resolves a red flag,
8 should the pharmacist make a note of that?

9 A. Not -- no.

14:21:42 10 Q. As long as the notes are there, that's adequate?

11 A. Correct.

12 Q. Whoops. But those notes should be readily
13 available to the pharmacist, right?

14 A. Readily available and understandable.

14:21:57 15 Q. Okay. And did you see any evidence of that based
16 upon the 8,000 you looked at?

17 A. No, sir.

18 Q. Now, that duty to document resolution of red flags,
19 do you consider that part of corresponding
14:22:15 20 responsibility?

21 A. Yes, sir.

22 Q. And by the same token, if those exact words
23 "Document red flags" are not used, does that mean you
24 don't need to do it?

14:22:30 25 A. No, sir.

1 It's explained in other language in the
2 regulations and in the guidance documents from the DEA.

3 Q. And is that consistent with your experience?

4 A. Yes, sir.

14:22:44 5 Q. Is that consistent with what you've seen in your
6 role overseeing the National Association of the Boards of
7 Pharmacy?

8 A. Yes, sir.

9 Q. Is that consistent with the interactions you've had
14:22:56 10 with the DEA?

11 A. Yes, sir.

12 Q. Is that consistent with the interactions you've had
13 with the various chain pharmacies?

14 A. Yes, sir.

14:23:03 15 Q. Now, if we look, for example, at some of the
16 Walgreen's historical notes that could be aligned with
17 the notes that you have, you've already testified about
18 the note from Walgreen's that talked of "508 days of
19 Oxycodone/Acetaminophen tabs and previous prescriptions
14:23:42 20 for this generic entities may exceed the recommended
21 adult duration of one to 30 days," do you remember
22 testifying about this note?

23 A. Yes, sir.

24 Q. Now, if you had had the chance to go back and look
14:23:56 25 at the entire history field associated with this patient,

1 and I'll put it up here, as associated with that
2 prescription number 1299624, you've got "Walgreen"? Can
3 you read that?

4 A. It looks like it says "prescription consultation
14:24:25 5 request."

6 Q. All right. Any comments there?

7 A. No, sir.

8 Q. Does that resolve the red flag for you looking at
9 that historical note?

14:24:34 10 A. No, sir.

11 Q. What about the next historical note? Does it
12 resolve the red flags?

13 A. No, sir.

14 Q. Does the next historical note resolve the red
14:24:43 15 flags?

16 A. No, sir.

17 Q. Does the next historical note resolve the red
18 flags?

19 A. Not all of the red flags, sir.

14:24:50 20 Q. It does have a prescriber comment of "Pain
21 management."

22 Does that change anything?

23 A. Not the overall picture, but it may address one of
24 the red flags that was identified with this prescription.

14:25:02 25 Q. The next historical note, does it resolve the red

1 flags?

2 A. No, sir.

3 Q. The last historical note, does it resolve the red
4 flags?

14:25:18 5 A. No, sir.

6 Q. So if we look at the historical notes for the
7 prescription that you talked about, do you find red flag
8 resolution?

9 A. No, sir.

14:25:31 10 Q. Similarly, you were shown another example or you
11 gave another example of a prescription from Walgreen's
12 that did not properly document a resolution of red flags
13 and yet was still dispensed.

14 Do you remember this one?

14:25:56 15 A. Yes, sir.

16 Q. You were asked a lot about it during redirect -- or
17 cross-examination.

18 Remember those questions?

19 A. Yes, sir.

14:26:05 20 Q. All right. Let's look at the actual notes fields
21 from prescription number 740278 and tell us if you had
22 looked at these historical note fields, if it -- let's
23 see, here we go -- does it resolve the red flags?

24 A. No, sir.

14:26:24 25 Q. What about the next entry?

1 A. No, sir.

2 Q. What about the next entry?

3 A. No, sir.

4 Q. What about the next entry?

14:26:33 5 A. No, sir.

6 Q. What about the next entry?

7 A. No, sir.

8 Q. What about the last entries? Whoops.

9 A. No, sir.

14:26:41 10 Q. By the way, so the jury has an idea of time, did
11 you get all of these prescriptions, were they all
12 produced, the 8,000, years ago for you to study?

13 A. No, sir.

14 Q. When did we finally get the 8,000 and get them into
14:27:06 15 your hands for you to study?

16 A. Some of the data I received probably about a month
17 to 10 weeks ago, and then some of the data came in just
18 about a week before my deposition, so about two weeks
19 ago.

14:27:21 20 Q. Instead of looking at more examples of Walgreen, I
21 want to shift to CVS.

22 You spoke about this CVS prescription being
23 an inadequate resolution of red flags, at least an
24 inadequate documenting.

14:27:51 25 MR. DELINSKY: Objection. Scope, Your

1 Honor.

2 MR. LANIER: I think this is what they
3 asked him on, Judge.

4 THE COURT: Overruled.

14:27:56 5 BY MR. LANIER:

6 Q. If --

7 THE COURT: I recall some questioning on
8 this, so --

9 MR. DELINSKY: Not from me, Your Honor.

14:28:07 10 This was from Mr. Lanier's direct.

11 MR. LANIER: Okay. Judge, in the interest
12 of time, I'll move on if he's not contesting this.

13 THE COURT: All right.

14 MR. LANIER: If there's no contest, I'll
15 move on.

14:28:16 16 BY MR. LANIER:

17 Q. Let's talk about Giant Eagle for a moment, and I
18 think that there may have been some miscommunication with
19 the Giant Eagle attorney. That's my comment in red --

14:28:42 20 MS. SULLIVAN: Objection, Your Honor, move
21 to strike the question.

22 THE COURT: I'll strike the comment, and it
23 doesn't matter with the attorney.

24 You can ask the question.

14:28:48 25 MR. LANIER: All right.

1 BY MR. LANIER:

2 Q. Sir, I want to talk to you about that issue of the
3 prescription that was dated 2010 that was filled in 2012
4 that y'all went back and forth and back and forth on.

14:29:03 5 Do you remember that?

6 A. Yes, sir.

7 Q. All right. First of all, Ms. Sullivan, the Giant
8 Eagle lawyer, kept trying to tell you that this first
9 column is the column when the prescription was filled, as
14:29:19 10 opposed to what it says here the prescription identifiers
11 years.

12 Can you explain the difference between a
13 prescription year and the date of fillment?

14 A. The prescription year would be when the
14:29:35 15 prescription actually was written.

16 Q. And are prescriptions often written that allow for
17 refills or phoned in refills, or something like that?

18 A. Except for Schedule IIs, yes, sir.

19 Q. And so can you have a prescription that is written
14:29:57 20 in the year 2010 where the filling of that prescription
21 is done in 2012?

22 A. It's -- yes, sir, it's possible.

23 Q. Okay. And because you were only given a random
24 selection of prescriptions, does it eliminate your
14:30:18 25 ability to see whether or not this was something that was

1 being filled routinely?

2 A. Yes.

3 Q. And if you continue to look, is there anything
4 that's on here that's inconsistent with your opinions?

14:30:35 5 A. No, sir.

6 Q. And if Giant Eagle got the dates wrong, does that
7 change your opinion of whether or not the red flags are
8 right?

9 MS. SULLIVAN: Objection.

14:30:44 10 Lacks foundation. Argument, lawyer
11 argument, Your Honor.

12 THE COURT: Overruled.

13 A. No, sir.

14 As I looked at this, the principal
14:30:54 15 identifier is the prescription number or the prescription
16 ID that was used for the data set.

17 Years ago, when I was in college, we used
18 our Social Security numbers as IDs, which is unheard of
19 now, but they would post test scores based on your Social
14:31:11 20 Security Number.

21 The prescription number, an identifier, is
22 the key to everything that happens with that
23 prescription. It's like your last name or whatever the
24 file would be.

14:31:20 25 So I could not assume anything else except

1 that this was all related to that prescription.
2 Otherwise, it should not have been filed with that
3 prescription. It's just against all of the recordkeeping
4 standards and standards of practice to mix and match
14:31:36 5 prescriptions within a patient profile or within a
6 document.

7 Q. Thank you.

8 Next part of dispensing. A question that
9 was asked of you by the CVS lawyer concerned active
14:31:52 10 cumulative Morphine equivalent doses.

11 Do you remember that subject?

12 A. Yes, sir.

13 Q. Here's my question.

14 Does an ACME score of zero mean there's no
14:32:03 15 need to do remaining due diligence on red flags?

16 A. No, sir.

17 Q. Do you still do due diligence on the other red
18 flags?

19 A. Yes, sir.

14:32:11 20 Q. And is -- if a company's got a program that when
21 the ACME is zero, if there's a program in place that says
22 you can ignore the other red flags, is that consistent
23 with your understanding of good practice?

24 A. No, sir.

14:32:27 25 MR. DELINSKY: Objection.

1 Argumentative, Your Honor.

2 THE COURT: Overruled.

3 BY MR. LANIER:

4 Q. Okay. Next stop on the road.

14:32:38 5 I want to talk to you about policies.

6 Okay?

7 A. Yes, sir.

8 Q. Let's begin with some questions you were asked
9 about the size of Giant Eagle.

14:32:53 10 Do you remember those questions?

11 A. Yes, sir.

12 Q. Does size make any difference at all on the
13 application of the law?

14 A. Size doesn't matter, sir.

14:33:05 15 Q. Does size make any difference at all in good
16 dispensing practice?

17 A. No, sir.

18 Q. Does size allow anyone who is a registered pharmacy
19 with a licensed pharmacist to do shortcuts?

14:33:27 20 A. The standards of care requirements cut across all
21 pharmacies, whether it's one pharmacy that fills 10
22 prescriptions a day, or a chain that fills thousands or
23 millions of prescriptions a year.

24 Q. All right. Ms. Sullivan with Giant Eagle also
14:33:42 25 asked you about the law. It was one of her exhibits, and

1 she asked you specifically about 21 C.F.R. 1306.04, the
2 purpose of issue of prescriptions.

3 Do you remember those questions?

4 A. Yes, sir.

14:33:57 5 Q. And she asked you about this language that she
6 highlighted with you, "The responsibility for the proper
7 prescribing and dispensing of controlled substances is
8 upon the prescribing practitioner, but a corresponding
9 responsibility rests with the pharmacist who fills the
14:34:15 10 prescription."

11 That's your testimony, right?

12 A. Yes, sir.

13 Q. And then she pointed out that the "Person knowingly
14 filling such a purported prescription" shall be subject
14:34:29 15 to penalties.

16 Do you see that word "Knowingly"?

17 A. Yes, sir.

18 Q. Explain how that is understood and applied.

19 MR. DELINSKY: Objection, Your Honor.

14:34:39 20 Calls for a legal conclusion.

21 MR. LANIER: I'll reask it, Judge.

22 BY MR. LANIER:

23 Q. Would you explain from the perspective of the
24 pharmacist how you understand that to be applied?

14:34:50 25 A. As a pharmacist, I cannot give the excuse that I

1 didn't know or I was unaware of my corresponding
2 responsibility.

3 And because it's something that's taught in
4 pharmacy school, part of the law curriculum, part of
14:35:05 5 guidance from the DEA, and part of the information the
6 State Boards of Pharmacy provide, I as a pharmacist can't
7 say I don't know or I wasn't aware of the corresponding
8 responsibility and red flags.

9 That defense was used in one of the cases
14:35:22 10 cited where the expert witness said pharmacists are
11 unaware of red flags and red flag is not a common term,
12 and the Administrative Law Judge in that case ruled
13 against that and said, "No, red flags are known and
14 should be known to the pharmacists and red flags are part
14:35:38 15 of corresponding responsibility."

16 Q. Can a pharmacist or their company be willfully
17 blind to the effects of their dispensing?

18 MR. DELINSKY: Objection. Calls for a
19 legal conclusion, Your Honor.

14:35:54 20 MR. LANIER: I don't think so.

21 THE COURT: Overruled.

22 If he -- you have to ask -- answer this in
23 your, your experience as a pharmacist, sir.

24 MR. LANIER: Yes, sir.

14:36:04 25 A. As a pharmacist, I would say a company cannot

1 ignore their responsibility or say that it doesn't exist,
2 and I don't know what willfully would mean in legal
3 terms, but that would be what a pharmacist would, I as a
4 pharmacist, I would interpret it.

14:36:19

5 BY MR. LANIER:

6 Q. All right. On policies, you were asked whether or
7 not you reviewed the refuse to fill documentation that
8 Walmart produced.

9 Remember that question?

14:36:28

10 A. Yes, sir.

11 Q. Okay. And you said that you knew of a program but
12 you didn't see the information.

13 Do I have that right?

14 A. Yes, sir.

14:36:35

15 Q. Here's my question: Did we call on you and retain
16 you to opine on Walmart's refusal to fill policy?

17 A. No, sir.

18 Q. Is that part of your expert opinion in this case?

19 A. No, sir.

14:36:50

20 Q. If we had called on you to do that, could you have?

21 A. Yes, sir.

22 MS. FUMERTON: Objection. Outside the
23 scope.

24 THE COURT: Overruled. Overruled.

14:37:06

25

1 BY MR. LANIER:

2 Q. Next issue.

3 You were shown Walmart -- Walgreen's,
4 excuse me, Your Honor, let me start that over.

14:37:23 5 You were shown Walgreen's Plaintiffs'
6 Exhibit 17230, which was a target drug good faith
7 dispensing checklist?

8 MR. SWANSON: I object, Your Honor. I
9 didn't show this document.

14:37:36 10 MR. LANIER: I think it was attached to the
11 exhibit that he used, but if he's not fussing it, Your
12 Honor, I'll pull it down.

13 THE COURT: Okay. I don't recall
14 Mr. Swanson using that one.

14:37:47 15 MR. LANIER: Okay.

16 THE COURT: I mean, it could have been
17 attached, but a lot of things could have been attached.

18 MR. LANIER: Then I'll move on, Your Honor,
19 in the interests of time.

14:37:53 20 Thank you.

21 BY MR. LANIER:

22 Q. Now, Giant Eagle specifically asked you through
23 their attorney, Ms. Sullivan, about second-guessing
24 prescribing doctors, and she kept using that term
14:38:06 25 "Second-guessing."

1 Do you remember that?

2 A. Yes, sir.

3 Q. Is second-guessing a term that's frequently used by
4 you or others in the pharmacist profession?

14:38:19 5 A. No. Second-guessing, pharmacists refer to it as
6 simply need or responsibility to be that filter to make
7 sure patients receive the right medications.

8 Q. And if we asked the question, if Giant Eagle policy
9 is to never second-guess a doctor's prescription, would
14:38:37 10 that be a good policy?

11 MS. SULLIVAN: Objection, Your Honor.
12 Lacks foundation. Lawyer argument.

13 THE COURT: Yeah, I'll sustain that.

14 BY MR. LANIER:

14:38:43 15 Q. All right. Sir, would it be a good policy to
16 automatically fill a prescription?

17 A. Without doing the Drug Utilization Review or red
18 flag review, no, sir.

19 Q. Okay. Do pharmacists -- are pharmacists properly
14:39:02 20 taught to make sure that a prescription is the right
21 prescription?

22 A. Pharmacists are taught that, and they're held
23 responsible. If they dispense that prescription and it
24 harms the patient or it was the wrong dose, the wrong
14:39:15 25 drug, that's part of what the pharmacist is held

1 accountable for by licensure.

2 Q. Okay. Now, you were also asked questions by
3 Ms. Sullivan about the Giant Eagle bonus structure, and
4 y'all went back and forth on the math.

14:39:34 5 Remember that?

6 A. Yes, sir.

7 Q. I'm not sure I followed it, but I want to make sure
8 your answer is on the record.

9 MS. SULLIVAN: Objection, Your Honor.

14:39:40 10 Move to strike the lawyer colloquy.

11 MR. LANIER: Judge, I'll just ask the
12 question.

13 THE COURT: All right. Let's ask a
14 question, please.

14:39:46 15 BY MR. LANIER:

16 Q. Sir, would you please explain what you were trying
17 to explain to Ms. Sullivan when she was asking you
18 questions?

19 A. Sure.

14:39:54 20 The question to me was could I just equate,
21 overall, Giant Eagle's percentage of prescriptions for
22 noncontrolled and controlled.

23 Is that the area, sir?

24 Q. Yes. I think she showed you the pharmacist's
14:40:11 25 calculation that maximized at one percent and skipped

1 over the pharmacy team leader that maximized at three
2 percent.

3 MS. SULLIVAN: Objection, Your Honor.
4 Argument and colloquy.

14:40:19 5 MR. LANIER: That's not, Judge.

6 THE COURT: Oh, that, I'll overrule that.

7 It's on the back of it. He said you
8 weren't shown that. I think that's right.

9 BY MR. LANIER:

14:40:28 10 Q. So please look at what she showed you, first, and
11 explain to the jury your math?

12 A. So I think the question was if overall Giant Eagle
13 dispensed 10 percent of all their drugs for controlled
14 substances would that make the conversion over so that
14:40:48 15 the pharmacist salary or bonus would be tied at almost a
16 10 percent or .1 percent of that.

17 And the reason the math didn't work out for
18 me that way or to make that assumption is that a
19 pharmacy, each pharmacy has a number of drugs that they
14:41:04 20 called fast movers, which means based upon their patient
21 population and the prescribers in the area, they dispense
22 more of those medications than the other medications.

23 For a number of years during the height of
24 the opioid epidemic, Vicodin or the Hydrocodone
14:41:21 25 combination product was the number one dispensed drug in

1 the entire United States.

2 Out of 200 drugs, because industry
3 publishes the top 200, that was the number one dispensed
4 drug by a wide margin across all of the U.S.

14:41:37 5 So, therefore, you may have a pharmacy
6 that's dispensing Hydrocodone as the top drug of that
7 pharmacy that would totally skew the percentage of
8 controlled substances to noncontrolled substances, and
9 then when you look at the overall data of the company,
14:41:56 10 the overall data then may make that look like 10 percent
11 because there would be a number of pharmacies that aren't
12 dispensing controlled substances, but it wouldn't give
13 you an accurate picture of that pharmacy or the
14 percentage.

14:42:09 15 So I was hesitant to make that
16 extrapolation because maybe it's nine percent or 10
17 percent Hydrocodone and not so much of the other
18 controlled substances.

19 The other reason is in other cases that
14:42:24 20 I've looked at, because people are aware of this metric,
21 people abusing and diverting drugs in those cases require
22 patients to buy noncontrolled drugs with their controlled
23 substances so they could alter their percentage and keep
24 it low.

14:42:44 25 Q. How does that work?

1 Explain to me that. I'm not tracking with
2 you, but explain that.

3 A. So when a patient would go see a doctor that was
4 involved in the cases I looked at, the doctor would write
14:42:57 5 a prescription for an opioid, and then also write a
6 prescription for a noncontrolled substance, maybe
7 something for stomach disorder, indigestion, gastric
8 reflux, and tell the patient they had to get both
9 prescriptions filled. And then when the patient went to
14:43:14 10 the pharmacy, some of the pharmacies that were involved
11 in these schemes would only fill the opioid if the
12 patient also filled that noncontrolled substance.

13 So patients and others involved in abuse
14 and diversion were aware of that metric, and, therefore,
14:43:30 15 they would use the noncontrolled-to-controlled substance
16 percentage to hide what they were doing as well.

17 So I couldn't make that extrapolation to
18 say, yes, that's true, because of how that number may be
19 inaccurate and how people have been misusing that to hide
14:43:45 20 abuse and diversion.

21 Q. All right. Last stop on the road, your National
22 Association of Boards of Pharmacy.

23 You were asked a number of questions by
24 different lawyers about that, and I want to put them up
14:44:02 25 here and give you a chance to explain.

1 First of all, the National Board of
2 Association & Purdue Programs that you were asked about
3 on Friday, remember those?

4 A. Yes, sir.

14:44:19 5 Q. Here's my question. Did the National Association
6 of Boards of Pharmacy let Purdue pay doctors to present
7 on opioids?

8 A. No, sir.

9 Q. Was there ever any point in time where the NABP let
14:44:37 10 Purdue put their spin on medicines?

11 A. No, sir.

12 Q. Did you ever allow Purdue to bring in doctors to
13 train your employees at the National Association of
14 Boards of Pharmacy?

14:44:57 15 A. No, sir.

16 Q. When the National Board of Association of
17 Pharmacies put out a Survey of Pharmacy Law in 2009,
18 where Purdue paid for this to be mailed to pharmacists
19 around the country, remember that?

14:45:19 20 A. Yes, sir.

21 Q. My question in that regard is this: Was there
22 anything in this mail-out that was persuading people to
23 write or to dispense opioid prescriptions?

24 A. No, sir.

14:45:40 25 Q. Would you have allowed Purdue to come in and to

1 teach your association about opioids and how they should
2 be handled?

3 A. No, sir.

4 Q. Thank you.

14:45:57 5 MR. LANIER: Your Honor, I pass the
6 witness.

7 THE COURT: Okay.

8 MS. SULLIVAN: Your Honor, if I might, just
9 two follow-up questions.

14:46:05 10 THE COURT: That's fine. If you
11 can -- whatever, whatever order you wish.

12 So start with Ms. Sullivan.

13 RECROSS-EXAMINATION OF CARMEN CATIZONE

14 BY MS. SULLIVAN:

14:46:27 15 Q. Mr. Catizone, good afternoon. Good afternoon,
16 jurors.

17 Mr. Lanier asked you about Giant Eagle
18 being small and somehow arguing the law didn't apply.

19 You didn't see any evidence in any of the
14:46:40 20 materials you reviewed that Giant Eagle ever made an
21 argument like that, that because we're smaller, the law
22 didn't apply?

23 A. Not on the documents I reviewed, no.

24 Q. Yeah. In fact, that's not true, the law applies
14:46:53 25 equally to everybody?

1 A. Yes.

2 Q. And no evidence Giant Eagle ever argued
3 differently, correct?

4 A. As far as I'm aware.

14:46:58 5 Q. Yeah.

6 A. No.

7 Q. Okay. And, Mr. Catizone, you were asked about the
8 bonus program for Giant Eagle, and you talked about
9 fast-moving prescriptions.

14:47:10 10 The truth is, sir, you have not done any
11 analysis of Giant Eagle's prescribing data to determine
12 which opioids, if any, were prescribed -- were filled
13 more often by the pharmacy?

14 A. Correct.

14:47:21 15 Q. Okay. And you talked about -- and I think,
16 Mr. Catizone, we can agree that almost all of your
17 testimony last week and today involved the Controlled
18 Substances Act and requirements under the Controlled
19 Substances Act?

14:47:35 20 A. Correct.

21 Q. Including your testimony about red flags?

22 A. Correct.

23 Q. And diversion, right?

24 And we can agree that the Drug Enforcement
14:47:47 25 Administration is the Government agency charged with

1 enforcing the Controlled Substances Act?

2 A. The DEA and the State Board of Pharmacy.

3 Q. Yeah. And as it relates to the Drug Enforcement

4 Administration that oversees the federal Controlled

14:48:04 5 Substance Act, Mr. Catizone, it's true, sir, that there

6 is no evidence that Giant Eagle was ever in violation of

7 the Controlled Substances Act according to the DEA?

8 A. Not with the DEA.

9 Q. Yes. And in fact, Mr. Catizone, there is no

14:48:20 10 evidence that the Drug Enforcement Administration ever

11 even filed an enforcement action alleging that Giant

12 Eagle violated the Controlled Substances Act, the DEA?

13 A. Not that I'm aware of.

14 MS. SULLIVAN: Okay. Thank you.

14:48:34 15 I have nothing further.

16 THE COURT: All right. Thank you,

17 Ms. Sullivan.

18 Mr. Swanson for Walgreen's.

19 MR. SWANSON: Thank you, Your Honor.

14:48:42 20 RECROSS-EXAMINATION OF CARMEN CATIZONE

21 BY MR. SWANSON:

22 Q. Good afternoon, Mr. Catizone.

23 A. Good afternoon, sir.

24 Q. I just have a few follow-up questions.

14:48:55 25 I wanted to clear something up from your

1 redirect.

2 We've talked a lot last week and today
3 about this set of 78-or-so-hundred prescriptions that you
4 looked at, right?

14:49:09 5 A. Yes, sir.

6 Q. And so it was 2,000 of those prescriptions samples
7 for Walgreen's?

8 A. Yes. Approximately, sir.

9 Q. Give or take?

14:49:17 10 A. Yes.

11 Q. Approximately 2,000.

12 And in response to a question from
13 Mr. Lanier, you said you were very surprised that in that
14 set of 2,000 prescriptions, you didn't see any refusals
14:49:27 15 to fill in that data set.

16 Do you remember saying that to Mr. Lanier?

17 A. Yes, sir.

18 Q. All right. And you now know, I take it, that the
19 reason you didn't see any refusals to fill in that data
14:49:40 20 set is because that data set was taken from only

21 prescriptions that were filled by Walgreen's, right?

22 A. That were dispensed, yes, sir.

23 Q. Yeah. So the 2,000 you saw, those were all
24 dispensed; you wouldn't expect to see any refusals to
14:49:54 25 fill in that file, right?

1 A. I would have expected something in the notes and
2 history, but for the ones that were dispensed, yes, I
3 wouldn't expect that unless there was something in the
4 history or the notes.

14:50:06 5 Q. Because those 2,000 prescriptions, they were all
6 filled, they were all dispensed, right?

7 A. Yes, sir.

8 Q. Okay. And what you and I went through when I asked
9 you some questions on cross-examination were some actual
14:50:17 10 refusals to fill that Walgreen's pharmacists had not
11 dispensed, right?

12 A. Yes, sir.

13 Q. And those were documents that the plaintiffs'
14 lawyers hadn't shown you before, right?

14:50:27 15 A. Again, whatever I reviewed, they sent over.

16 I'm not sure whether they had possession or
17 not, sir, but yes.

18 Q. Okay. So when Walgreen's in this litigation
19 produced its files of its refusals to fill, that's just
14:50:42 20 not something you've seen because it was not provided to
21 you by the lawyers, right?

22 A. Yes, sir.

23 Q. And that's the same for the other defendants, true?

24 A. Yes, sir.

14:50:49 25 MR. SWANSON: Thank you.

1 I don't have anything else.

2 THE COURT: All right. Thank you,

3 Mr. Swanson.

4 Anything from Walmart or CVS?

14:50:57 5 MS. FUMERTON: No.

6 MR. DELINSKY: Nothing from CVS, Your

7 Honor.

8 MS. FUMERTON: Nothing else from Walmart.

9 Thank you.

14:51:02 10 THE COURT: All right. Thank you,

11 Dr. Catizone.

12 You may step down.

13 (Witness excused.)

14 THE COURT: Plaintiffs may call their next

14:51:30 15 witness, please.

16 MR. LANIER: Thank you, Your Honor.

17 Our next witness is Joe Rannazzisi. He is

18 retired from the DEA and he will testify about his

19 actions at the DEA.

14:52:30 20 THE COURT: All right. Mr. Rannazzisi, if
21 you could raise your right hand, please.

22 JOSEPH RANNAZZISI,

23 of lawful age, a witness called by the Plaintiffs,

24 being first duly sworn, was examined

14:52:41 25 and testified as follows:

1 THE COURT: Thank you.

2 And you may take off your mask while
3 testifying.

4 MR. LANIER: May it please the Court.

14:52:54 5 DIRECT EXAMINATION OF JOSEPH RANNAZZISI

6 BY MR. LANIER:

7 Q. Mr. Rannazzisi, I have taken your deposition once
8 before and I watched a second deposition via Zoom.

9 Fair?

14:53:11 10 A. Yes, sir.

11 Q. And then met you face-to-face in the sense of
12 outside of the deposition for the first time last night
13 when we spent, I don't know, less than an hour talking
14 about your testimony today.

14:53:26 15 Is that right?

16 A. Yes, sir.

17 Q. And in that regard, sir, I've got a roadmap of
18 where I want to take you today and tomorrow morning.

19 I don't think we'll finish with you this
14:53:35 20 afternoon.

21 But I want to talk about your experience,
22 and then I want you to explain some things relative to
23 the DEA, and then we're going to talk about some of your
24 interactions with the defendants in this case.

14:53:48 25 All right?

1 A. Yes, sir.

2 Q. So with that as our roadmap, let's start with your
3 experience.

4 First of all, tell the jury a little bit
14:54:04 5 about you, who you are. Introduce yourself to them.

6 A. Good afternoon.

7 My name is Joe Rannazzisi. I retired from
8 the Drug Enforcement Administration as the Deputy
9 Assistant Administrator of the Office of Diversion
14:54:20 10 control. I was also a Deputy Chief of Operations.

11 I worked most of my career in the
12 three -- in the field in the three-state area of
13 Michigan, Ohio and Kentucky.

14 During that time period, I worked all
14:54:39 15 different types of investigations, including homicide,
16 clandestine laboratory, and general undercover cocaine
17 and heroin investigations.

18 Q. All right. Where do you live today?

19 A. Today I live in Virginia.

14:54:57 20 Q. And you drove over here this weekend, I guess?

21 A. Yes, I did.

22 Q. All right. You used to have one of these fancy DEA
23 badges?

24 A. I -- I still do, but it says "Retired."

14:55:15 25 Q. Oh. I mean, did they give you one of them jackets

1 that had the yellow printing like we see on TV?

2 A. Yes, I had one of those. Yes, I did.

3 Q. Did you, like, go bust open crack houses and stuff
4 in your day?

14:55:28 5 A. Early in my career I -- I was on the street
6 enforcement crew, yes.

7 Q. All right. Before we get to your DEA career, I
8 think it's helpful for us to understand some of your
9 experience.

14:55:39 10 We're going way back here. You and I are
11 both the same age, right?

12 A. Yes, sir.

13 Q. So you must have graduated from high school, I'm
14 guessing, '79, '78, somewhere in there?

14:55:53 15 A. 1979.

16 Q. Where did you go to high school?

17 A. Freeport High School, Freeport, New York, on Long
18 Island.

19 Q. All right. And you graduated from high school.

14:56:02 20 Where did you go from there?

21 A. Butler University, Indianapolis, Indiana.

22 Q. And at Butler University, what kind of degree did
23 you get?

24 A. My degree was in pharmacy, Bachelor of Science
14:56:18 25 degree in pharmacy.

1 Q. And what year did you get it?

2 A. 1984.

3 Q. And are you or did you become a licensed
4 pharmacist?

14:56:31 5 A. Yes, sir, I did.

6 I'm licensed to practice pharmacy in the
7 State of Indiana.

8 Q. And have you practiced as a pharmacist in your
9 life?

14:56:41 10 A. Yes, I have.

11 Q. When did you do that?

12 A. From 1984 to 1986.

13 Q. All right. And then, well, side note, where did
14 you practice pharmacy?

14:56:59 15 A. I interned at a Polk's Drug in North, North
16 Indianapolis, and once I graduated and passed my pharmacy
17 boards I worked at an outpatient clinic at the Veteran's
18 Administration Hospital, and then inpatient for a while,
19 too.

14:57:23 20 Q. And then from there, is that when you went into the
21 DEA?

22 A. Yes, sir.

23 Q. Tell the jury why you went into the DEA.

24 A. I grew up in a neighborhood on Long Island where it
14:57:37 25 was almost all public servants, people who would either

1 be firemen, policemen, worked for the town or the village
2 or the county, or even the state.

3 During that time period a lot of my -- my
4 friends' parents were either firemen or police officers,
14:57:54 5 and at one point in time while I was growing up there was
6 a news story about a police officer, a DEA agent, he was
7 actually in the Bureau of Narcotics and Dangerous Drugs,
8 which was before DEA, who was involved in an undercover
9 deal. And during the deal he was shot and killed.

14:58:16 10 And that was one of the things that stuck
11 in my mind, and I knew I was going to go into law
12 enforcement eventually, and that's what drew me towards
13 DEA.

14 Q. All right. So you started with the DEA what year?

14:58:31 15 A. 1986.

16 Q. And you stayed with the DEA until?

17 A. 2015, October 31st, 2015.

18 Q. All right. During that time period, I think it
19 would help the jury to understand what your different
14:58:49 20 jobs were and positions were.

21 So how did you start out in 1986?

22 A. In 1986 to 1988 I was a diversion investigator.

23 I investigated violations of the Controlled
24 Substances Act related to pharmaceuticals and chemicals.
14:59:10 25 That was in Indianapolis, Indiana.

1 Q. And the jury's heard that word "diversion," but
2 just to make sure we're clearly using it the way the DEA
3 does, how do you define "Diversión"?

4 A. Diversion is the illegal movement of
14:59:26 5 pharmaceuticals from the legitimate stream of commerce
6 into the illegitimate market.

7 Q. All right.

8 A. Pharmaceuticals and chemicals.

9 Q. So you do diversion investigation for several
14:59:38 10 years, and then in 1988 what do you become?

11 A. I become a special agent in 1988.

12 Q. And what is a special agent for the DEA?

13 A. Well, a diversion investigator generally
14 concentrates on pharmaceuticals and chemicals. A special
14:59:58 15 agent conducts all the wide range of controlled substance
16 and chemical investigations.

17 So they could be on street enforcement

18 doing, you know, buy busts, small amounts of drugs,

19 conspiracy crews that actually do long-term

15:00:14 20 investigations. Undercover investigations, where you're
21 actually meeting drug dealers to purchase drugs.

22 Clandestine lab investigations, where you investigate,

23 follow chemicals to a place where they're manufacturing,

24 illegally manufacturing controlled substances like

15:00:36 25 methamphetamine, amphetamine, things like that.

1 Q. Did you -- did you actually go undercover yourself?

2 A. Yes, sir, I did, on numerous occasions.

3 Q. Back then, did you have more hair?

4 A. I had -- I had long hair, yes. I did have long
15:00:55 5 hair.

6 Q. And --

7 A. As a matter of fact, it was pretty long for a
8 while.

9 Q. And so did you have, like, an undercover name that
15:01:03 10 you're allowed to tell us?

11 A. I don't know if I'm allowed to tell you but, yeah,
12 most of us had another personality, yes.

13 Q. You did this work as a special agent for how many
14 years?

15:01:21 15 A. From 1988 until I became a supervisor in 1997.

16 Q. And what kind of a supervisor did you become?

17 A. I supervised the Homicide Task Force in Detroit,
18 Michigan.

19 Q. And the Homicide Task Force in Detroit, what kind
15:01:51 20 of work did the DEA Homicide Task Force do as opposed to
21 FBI or someone else?

22 A. We strictly investigated drug-related homicides,
23 both cold cases and active investigations.

24 Q. Okay. Somewhere in here you decided to go to law
15:02:15 25 school.

1 A. Yes, sir.

2 Q. What made you decide to go to law school?

3 A. When you're doing these investigations
4 you're -- you're constantly being told what's legal and
15:02:30 5 what's not, and what you can do and what you can't do,
6 what we can prosecute and what we can't prosecute.

7 And I just found it fascinating that there
8 were a lot of rules that needed to be, you know, need to
9 be addressed.

15:02:44 10 So I decided I was going to learn for
11 myself exactly what the law was, and I've always been
12 fascinated with the law.

13 Q. So you went -- I'll slip back over here to your
14 education.

15:02:58 15 You went to law school where?

16 A. Detroit College of Law, Michigan State University.

17 Q. And did you complete law school?

18 A. Yes, I did.

19 Q. And did you take the Bar exam?

15:03:13 20 A. Yes, sir, I did.

21 Q. Did you pass?

22 A. Yes, sir, I did.

23 Q. So are you a licensed attorney as well as a
24 pharmacist?

15:03:22 25 A. I am. I'm a member of the Michigan State Bar.

1 Q. Do you keep your Bar up?

2 A. Yes, sir, I do.

3 It's due just before Thanksgiving.

4 Q. And do you keep your license as a pharmacist up?

15:03:41 5 A. Yes, sir, I do.

6 Q. Now, were you going to law school at the same time
7 you were working for the DEA?

8 A. Yes, sir, I was.

9 Q. How did you manage that?

15:03:53 10 A. Law school was at night, and I switched my hours so
11 when I was a special agent I moved my hours to work a lot
12 of evening, midnight hours.

13 So midnight to 8:00 or 10:00 to 6:00 or
14 10:00 to 8:00, or whatever the hours worked at that point
15 in time. And then when I became a supervisor it was
16 close to the end of my time in law school, so it worked
17 out very well.

18 Q. All right. After -- what was your next position in
19 the DEA after supervisor?

15:04:29 20 A. I was transferred to headquarters sometime around
21 2000, right around January, January, February, 2000.

22 And I was assigned to the Domestic
23 Operations West section as one of the clandestine lab
24 coordinators in headquarters.

15:04:50 25 Q. And the headquarters for the DEA is where?

1 A. In Arlington, Virginia, right across from the
2 Pentagon.

3 Q. Right across from where?

4 A. The Pentagon.

15:05:08 5 Q. And what did you do, what was your job title when
6 you were transferred?

7 A. I was -- I was transferred as a group supervisor,
8 and when I got to headquarters I was a staff coordinator.

9 It's a supervisory position, a lower
15:05:28 10 supervisory position in DEA headquarters.

11 Q. All right. And how long did you stay in that job
12 at the DEA?

13 A. About a year-and-a-half, I guess.

14 Q. And what was your next position?

15:05:42 15 A. I was promoted to the section chief position in the
16 Dangerous Drugs and Chemicals section.

17 Q. And what did you do as a section chief in Dangerous
18 Drugs and Chemicals?

19 A. Worked all investigations involving synthetic drugs
15:06:08 20 and chemical investigations, and clandestine lab
21 investigations.

22 So anything that you could make, we
23 investigated, be it methamphetamine, amphetamine, MDMA,
24 Fentanyl. If you could make it, we investigated it.

15:06:26 25 Q. Okay. And you kept that job position how long?

1 A. Until about 2000, the end of 2002, beginning of
2 2003, I was transferred back to Detroit as an Assistant
3 Special Agent in Charge.

4 Q. And what is an Assistant Special Agent in Charge?

15:06:51 5 A. Assistant Special Agent in Charge works underneath
6 the Special Agent in Charge. His role is to -- the
7 day-to-day, to oversee day-to-day operations, ensure that
8 the Special Agent in Charge has all the information he
9 needs to make decisions.

15:07:09 10 But the Assistant Special Agent in charge
11 or the ASAC, his responsibility is to make sure that his
12 group or groups within the division are operating,
13 functioning as they should, and they have all of the
14 resources necessary to do their jobs.

15:07:26 15 Q. All right. Next job.

16 A. In 2004 I was transferred back to DEA headquarters
17 by Administrator Tandy as the Deputy Director for the
18 Office of Diversion Control.

19 Q. All right. Deputy Director, Office of Diversion
15:07:54 20 Control.

21 A. Yes, sir.

22 Q. And I meant to write down what you meant by
23 diversion.

24 Diversion, you define, as what?

15:08:04 25 A. The movement of pharmaceuticals, legitimate

1 pharmaceuticals and chemicals from the normal legitimate
2 stream of commerce into the illicit market.

3 Q. Can I just say moving pharmaceuticals from legal to
4 illegal market?

15:08:21 5 A. That would be perfect.

6 Q. All right. So as the Deputy Director for the
7 Office of Diversion Control, what types of activities
8 were you doing?

9 A. I handled day-to-day operations within the Office
15:08:45 10 of Diversion Control, and reported to the deputy
11 assistant administrator who oversaw that office.

12 My job was to make sure that he had all the
13 materials and information, resources, necessary to do his
14 job.

15:08:57 15 I also oversaw several sections within the
16 Office of Diversion Control, making sure, again, that
17 they function appropriately and efficiently.

18 Q. And then what was your next job after that?

19 A. Three months later they made me the Deputy Chief of
15:09:17 20 Enforcement Operations, Global Enforcement Operations.

21 Q. And your next job after that?

22 A. In 2005, July of 2005, they asked me to do both the
23 Global Enforcement Operations job and assist at the
24 Office of Diversion Control as the Acting Deputy
15:09:41 25 Assistant Administrator because then Deputy Assistant

1 Administrator Bill Walker was deployed to the Service.

2 So I took both jobs, I handled both jobs
3 for approximately six months.

4 Q. And after that, what did you do then six months
15:10:02 5 later?

6 A. The Administrator asked me to take over the Office
7 of Diversion Control as the full-time Deputy Assistant
8 Administrator.

9 Q. And that, I think, is part of what you were in for
15:10:15 10 the times that will be most relevant in this case.

11 Is that right?

12 A. Yes, sir.

13 Q. So Office of Diversion Control, when did you become
14 that lead, whatever the job title was?

15:10:32 15 A. January of 2016.

16 Q. January, 2006?

17 A. '6, 2006.

18 Q. All right. And as head of the Office of Diversion
19 Control, as the jury hears what your testimony's going to
15:10:48 20 be, when we walk through this, tell them what your job
21 responsibility was, please.

22 A. My jobs included the promulgation of regulations
23 under the Controlled Substances Act, the Code of Federal
24 Regulations, regarding any pharmaceutical or chemical
15:11:09 25 regs.

1 Generally that's done through passage of
2 laws and statutes.

3 I was also one of the liaisons to Congress
4 when it came to pharmaceuticals and chemicals, I briefed
15:11:25 5 Congress and appeared before Congress on numerous
6 occasions.

7 I was the liaison to federal, state and
8 local law enforcement agencies related to chemicals and
9 pharmaceuticals.

15:11:38 10 I oversaw all inspections and
11 investigations regarding pharmaceuticals and chemicals in
12 the U.S. and abroad.

13 I was -- I was responsible for going out
14 and talking to both the regulated community, parents,
15:12:01 15 teachers, law enforcement, attorneys, regarding all
16 aspects of diversion, chemical and pharmaceutical.

17 Q. All right. How many times do you think you
18 testified or spoke to Congress in your tenure?

19 A. I testified over 30 times before the different
15:12:26 20 committees of Congress.

21 I've spoken to Congress, different
22 committees, staffers, probably double that.

23 Q. All right. Now, since you've retired in October,
24 2015, what have you been up to?

15:12:48 25 A. I -- after I retired, I didn't do anything for a

1 few months.

2 I was trying to figure out what -- I was
3 trying to find myself, and then I decided I'd go work for
4 a small company. And that lasted about a year, and then
15:13:07 5 I started working with the states as they worked through
6 the opioid epidemic and started looking at litigation
7 against the regulated industry.

8 Q. And the jury needs to hear your role in that
9 regard.

15:13:29 10 You have been hired as an expert by a
11 number of different states to help them in their opioid
12 litigation, is that fair?

13 A. Yes, sir, it is.

14 Q. So, for example, have you been hired and worked for
15:13:45 15 the State of Ohio?

16 A. Yes, I have.

17 Q. And those states, when they hire you, do they pay
18 you?

19 A. Yes, sir, they do.

15:13:53 20 Q. And so the jury has a feel, what's your hourly
21 rate?

22 A. \$500 an hour.

23 Q. And you've made, over the last six years or however
24 long you've been doing this, five years, how much money
15:14:07 25 would you say you've made working as an expert for the

1 states and others who have hired you?

2 A. Since 2017, I made about \$930,000.

3 Q. So this has been a full-time job for you?

4 A. Yes, sir.

15:14:22 5 Q. And in that regard, are you appearing here as a
6 hired expert by me or anyone on our team?

7 A. No, sir.

8 Q. Are you here to testify as an expert witness?

9 A. No, sir.

15:14:41 10 Q. Have we served on the Government papers to have you
11 testify as a fact witness?

12 A. I believe that's what I'm here for, to testify as a
13 fact witness.

14 Q. And we've had to specify to the Government the
15:14:57 15 areas in which we plan on talking to you.

16 Fair?

17 A. That's correct.

18 And --

19 Q. Can you explain to the jury why that's important?

15:15:04 20 A. As a Government employee, any Government employee,
21 you're exposed to certain things that the Government does
22 not necessarily want to be out in the public view:
23 Privileged information, information regarding
24 investigative process, nonpublic information that you
15:15:26 25 receive during meetings and during briefings, and things

1 like that.

2 So the department allows me to testify here
3 under a letter, basically a letter directing me what I
4 can and can't talk about.

15:15:42 5 Q. And you're aware of the fact that the Government
6 has a lawyer in the courtroom with us right now who's got
7 an ability to object if we get outside those boundaries,
8 either side?

9 A. Yes, sir, there is.

15:15:55 10 Q. Now, in this regard, I want to make sure that we're
11 on the -- I need to talk to you about your testimony
12 because are there times in the past, for example, where
13 you have testified and actually testified as the
14 mouthpiece of the DEA?

15:16:26 15 A. In front of Congress, yes. Absolutely.

16 Generally, if I appear before Congress, I'm
17 appearing as the conduit for the administration, the
18 Department of Justice and DEA, to provide their views,
19 their position on certain matters.

15:16:48 20 And so they would generally select a senior
21 executive service officer or somebody in a position like
22 mine to appear and explain to Congress what we're doing,
23 how we're doing it, what resources we need, and why it's
24 happening.

15:17:02 25 Q. When you testified as a mouthpiece of the DEA and

1 you were giving DEA positions to Congress, were they
2 always something that you personally agreed with?

3 A. Not necessarily, no.

4 Q. But would you be required as the DEA mouthpiece to
15:17:20 5 say what you believe the DEA position to be that you'd
6 been asked to represent?

7 A. Yes, sir.

8 It's the position -- when a senior
9 executive goes before Congress, you're appearing there on
15:17:31 10 behalf of the administration, the department or the Drug
11 Enforcement Administration. You're not appearing as
12 yourself in your personal capacity.

13 So everything that's discussed, everything
14 that's written and provided to Congress is the
15:17:46 15 administration's position, not my own position.

16 Q. Now, as you are here today to testify as a fact
17 witness, and this is what I need to contrast, are there
18 going to be times where I'm asking you questions about
19 the DEA position on things based upon your experience and
15:18:09 20 your knowledge?

21 A. Yes, you will.

22 Q. But do I also have the liberty of asking you
23 questions about your personal experiences and knowledge
24 of the facts?

15:18:29 25 A. If, if they're public record facts, yes.

1 Q. Explain what you mean by that, personal opinions if
2 they're -- or personal facts if they're public facts.

3 A. Sure.

4 If I'm going to give you my personal
15:18:47 5 opinion, it's got to be based on -- on things that are in
6 the public view, things that would be available to you,
7 and I could be a conduit to explain what went on during
8 that time period.

9 I couldn't -- I couldn't just reach out and
15:19:03 10 take a fact that's not in the public domain and say,
11 "Well, this is what happened because of this, this and
12 this" and no one knew about it.

13 The Government wouldn't allow me to do that
14 because it's not available in the public domain.

15:19:17 15 Q. And is that important for the DEA's ability to
16 continue to do what it does?

17 A. Yes. It protects the integrity of the
18 investigations and the integrity of the investigative
19 process.

15:19:28 20 Q. All right. Then with that as the first stop of
21 your experience, let's go to the second stop, where we
22 start talking about the DEA.

23 Okay?

24 A. Yes, sir.

15:19:40 25 Q. I'm going to have you explain the DEA. We'll try

1 to keep, to some extent, a running tab of what you're
2 talking about.

3 First thing I want you to do is explain
4 what it means in terms of opiates to have a closed
15:20:18 5 system.

6 A. Sure.

7 The closed system of distribution is a
8 system that was created by Congress in the Controlled
9 Substances Act to ensure that we could account for every
15:20:35 10 amount of drug that's coming down from the raw material
11 level all the way down into the final pill form, into the
12 pharmacies, and then out to the patients.

13 It's a system of accountability. The
14 system of accountability involves recordkeeping, it
15:20:57 15 involves scheduling, it involves security, it involves
16 quota, it involves audits. Different aspects of the
17 closed system of distribution protect the integrity of
18 the closed system of distribution.

19 So theoretically I could go somewhere in
15:21:18 20 that supply chain and find out where the drugs went or
21 where they were diverted to.

22 It's a system that protects the integrity
23 of the controlled substance supply chain.

24 Q. All right. I've drawn a circle to represent that
15:21:33 25 closed system.

1 I want you to help us populate that,
2 please.

3 A. Okay.

4 Q. So what belongs in the circle?

15:21:43 5 Let's start with the opiate opium itself or
6 whatever it is, the raw materials that come from the
7 poppy?

8 A. Raw materials, yes.

9 So in the closed system, depending on if
15:21:57 10 the drug is synthetic or if the drug is a semisynthetic,
11 like Oxycodone, Hydrocodone, or if it's a pure opiate
12 like Morphine, the raw material comes in, it's brought
13 into the country or it's made in the country by a
14 manufacturer.

15:22:18 15 And that manufacturer, an importer to a
16 manufacturer and then manufacturer, could manufacture
17 what the Government allows them to manufacture.

18 From that manufacturing point, the drug is
19 inventoried and maintained until it is sent downstream to
15:22:42 20 either a dosage form manufacturer, or if it's in dosage
21 form to a distributor.

22 Every stop along the way throughout that
23 whole process, there's records. There's records of how
24 much was made, there's records of how much was produced,
15:23:00 25 how much was wasted during the production, how much went

1 into pill form, and where it went downstream.

2 Now, for a Schedule II controlled
3 substance, that form of record could be a 222 form or a
4 Schedule II controlled substance form. For Schedule III,
15:23:19 5 IV and V drugs it would be some type of invoice or
6 receipt.

7 But no matter what, any time there's
8 movement, there's documentation of that movement through.

9 And every time there's movement, there's
15:23:34 10 not only documentation of the movement through
11 recordkeeping, but there's also documentation of the
12 movement through a system called ARCOS. ARCOS is the
13 Automation of Reports and Consolidated Orders System, and
14 that system tracks drugs all the way through the chain.

15:23:53 15 That's another part of the closed system.
16 To maintain the integrity, you don't only have the
17 paperwork that you could go back and look at, but you
18 also have the ARCOS system for all Schedule I, II and III
19 narcotics.

15:24:10 20 Q. All right. I've got to interrupt you because I
21 want to make sure that I've got an ability to flow
22 through what you're saying and get it right.

23 This closed system, you started out by
24 saying it's imported or made by a manufacturer.

15:24:25 25 A. Yes.

1 Q. I've got that right.

2 And then it's inventoried.

3 A. Yes.

4 Q. All right. The jury has heard a little bit about
15:24:34 5 the DEA having a quota system --

6 A. Yes.

7 Q. -- for importing the raw materials.

8 Can you take a moment and explain the role
9 of the DEA in this importation?

15:24:49 10 A. Well, importation is separate from quota.

11 Importation involves the movement of raw
12 materials like concentrated poppy straw or Thebaine, or
13 any number of different types of raw product, into
14 the -- into the United States from growing countries,
15:25:07 15 countries that grow the poppy or countries that process
16 poppy.

17 The quota system attaches when we start
18 looking at their manufacturing process.

19 So if you're a manufacturer, and you're
15:25:22 20 manufacturing raw material into a what we call a basic
21 class, we'll say Oxycodone, that's a basic class, you
22 have a certain amount of drug that you need to meet all
23 of your contracts for all these other dosage form
24 manufacturers that are purchasing from you.

15:25:43 25 So what we will give you a quota based on

1 your contracts, based on your need, your assessed need,
2 based on a number of different factors, and all of that
3 is by statute. It's all in 21, U.S.C., 826, which is the
4 quota statute.

15:26:03 5 So anytime a controlled substance is moved
6 downstream, the opioid controlled substance is moved
7 downstream, it starts with a quota that's granted to the
8 manufacturing companies.

9 Q. All right. So the DEA's got a quota on the
15:26:24 10 manufacturing.

11 This is inventoried, and then where does
12 the medicine go from there, the pharmaceutical go from
13 there?

14 A. From the manufacturers, once they're produced in
15:26:42 15 final dosage form and packaged, they would go to a
16 distributor.

17 The manufacturer would transfer them
18 eventually to a distributor.

19 Q. And distributor is a word of art in this arena, is
15:26:58 20 that fair?

21 A. Yes. They are also called wholesalers.

22 Q. Wholesalers?

23 A. Yes.

24 Q. And are records kept along the way?

15:27:14 25 A. Yes, sir.

1 Records have to be kept along the way.

2 That's part of the regulation, the statute.

3 Q. All right. And those records will show -- what do
4 they show from the manufacturer to the distributor?

15:27:27 5 What will the records show?

6 A. Show the movement of whatever quantity of drugs
7 being moved from the manufacturer to the distributor, the
8 day it's transferred, the day it's received; the
9 quantity, the drug, the dosage form, the strength.

15:27:47 10 That's all the NDC number, the National
11 Drug Code number, so all of that is in the paperwork.

12 It shows the transfer, going from
13 manufacturer to distributor.

14 Q. And do the distributors, what do they do with the
15:28:06 15 drugs when they get them, the wholesaler?

16 A. Well, the distributor would put them in inventory,
17 and then start supplying their customers, which generally
18 hospitals, pharmacies, clinics, things like that.

19 And those drugs, part of this closed system
15:28:28 20 of distribution is the security of those drugs, so those
21 drugs, depending on what they are, a Schedule II
22 controlled substance would be stored in a vault at the
23 distributor location and at the manufacturer location.

24 If it's a Schedule III, IV or V drug, it
15:28:44 25 would be stored in a cage, what they called a controlled

1 substance cage.

2 So all along the way there's security
3 that's attached to the recordkeeping that's attached to
4 the flow of the drug downstream.

15:29:00 5 Q. And is the reason that these drugs are stored in
6 vaults and cages because of a concern over theft or
7 diversion?

8 A. Theft, diversion, and the nature of the drugs.

9 They're very dangerous. They're -- if they
15:29:15 10 are used inappropriately, they cause harm, so we want to
11 ensure that they're not leaking out of the system.

12 That's why the security is so important to
13 the system.

14 Q. So where do the pharmacies come into this closed
15:29:30 15 system? Where do I draw them?

16 A. Right next to the distributor.

17 Q. And are pharmacies also required to be registered?

18 A. Yes.

19 Everybody in the chain has to have a DEA
15:29:52 20 registration, so a manufacturer is registered as a
21 manufacturer, but they also distribute because a
22 manufacturer just doesn't manufacture and keep their drug
23 in inventory, it's got to go downstream.

24 So a manufacturer is automatically a
15:30:07 25 distributor.

1 A distributor is registered as a
2 distributor.

3 A pharmacy is registered as a pharmacy.
4 And the reason all -- that registration allows you or
15:30:17 5 gives you the authority to handle controlled substances.

6 So in the case of a pharmacy, the
7 pharmacy's registered but the pharmacist is not
8 registered. It's just the pharmacy.

9 Q. And then the pharmacies, I assume, get valid
15:30:41 10 prescriptions, and what goes on from there?

11 A. The pharmacies get prescriptions generally written
12 by prescribers, either doctors, dentists, mid-level
13 practitioner, a nurse practitioner, and what they do is
14 they take that prescription, they evaluate it, and then
15:31:06 15 they dispense medication if it meets the criteria for
16 dispensing the medication.

17 Q. And that's how it gets into the hands of the
18 consumer?

19 A. Yes, sir.

15:31:14 20 Q. And at that point it's out of the closed system?

21 A. At that point the closed system ends, because it's
22 in the hands of the person who should be taking the
23 medication, yes.

24 Q. You said records each step.

15:31:30 25 You talked of ARCOS as a record system.

1 Do the records need to be kept all the way
2 through until the drug leaves the closed system?

3 A. Yes, sir.

4 Every step of the way there's a record.

15:31:46 5 There's a check. Somewhere in that system in a readily
6 achievable format there should be a record of the
7 transfer, inventory, of the medication.

8 So when a DEA investigator walks in with a
9 notice of inspection and says, "I'm here to inspect, I
15:32:04 10 need to see your records, I need to see your
11 manufacturing records, I need to see your distribution
12 records, I need to see your prescription records and your
13 receipt records," they should be in a readily retrievable
14 format where the pharmacist or the distributor supervisor
15:32:21 15 or the manufacturer supervisor could turn around and say,
16 "Our records are over here. Let me help you find them,"
17 and should be able to go through and start the process of
18 the audit.

19 Q. All right. So you've walked us through the closed
15:32:35 20 system.

21 I want to focus a little bit more carefully
22 in the closed system, first, on distributors.

23 So can we talk about distributors for a
24 little bit?

15:32:48 25 A. Yes, sir.

1 Q. All right. You also called them wholesalers.

2 Explain why.

3 A. It's just another term for a distributor.

4 They take bulk drug that they receive at
15:33:02 5 whatever cost and then they turn around and cut that bulk
6 drug down to smaller sizes to be transferred to
7 pharmacies.

8 Q. All right. So the dispenser cuts bulk down and
9 then dispenses it?

15:33:22 10 A. Distributor.

11 Q. No, the distributor. I'm sorry, I messed up.

12 The distributor cuts the bulk down.

13 So is there specific laws that apply to
14 distributors?

15:33:34 15 A. Yes, sir.

16 Q. What are the key laws that apply to distributors?

17 A. Well, the first, all registrants, regardless of
18 where they are in the chain, they all must maintain
19 effective controls against diversion, which means they
15:33:56 20 have to have in place a system of security,
21 recordkeeping, that protects the drugs that they're
22 dealing with, the drugs that they're transferring, that
23 protects them from being moved out into the illegitimate
24 or illegal stream.

15:34:14 25 So everyone in that chain -- distributors

1 have a specific requirement that they maintain a system
2 where they could look at, identify, and then report a
3 suspicious order.

4 And a suspicious order is an order that's
15:34:39 5 basically going downstream to a pharmacy or other entity
6 that's of unusual size, unusual frequency, or deviating
7 substantially from the normal ordering pattern.

8 Q. All right. We've got to make a record on this, and
9 the jury needs to understand it, so let's break this
15:35:04 10 apart.

11 You said distributors must maintain a
12 system.

13 What do you mean by "System"?

14 A. It -- some type of functional method, so they could
15:35:23 15 look at all of their orders and determine if there's some
16 anomaly within their ordering pattern, something that is
17 suspicious, something that jumps out at them and says
18 "There's something wrong with this order, I have to
19 investigate it to find out why this order is so different
15:35:40 20 than other orders."

21 Q. Give -- give the jury an example.

22 I mean, what -- what in the world of these
23 wholesalers, what could be out there that would seem
24 suspicious?

15:35:57 25 Real life examples.

1 A. Back in 2006, we were experiencing a rise in
2 Internet pharmacies in the United States. An Internet
3 pharmacy is generally a pharmacy that's rogue, it's
4 operating outside the legal boundaries of the Controlled
15:36:23 5 Substances Act.

6 That whole system, that Internet pharmacy
7 system, worked on a system where you never saw a doctor
8 or a pharmacy. All you did was get online, run
9 "Hydrocodone without a prescription," and you'd get
15:36:40 10 200,000 hits.

11 You'd look for one that says "Buy
12 Hydrocodone now without a prescription," and you'd hit
13 their website. Their website would take you to an anchor
14 site or a pass-through site to an anchor site that would
15:36:56 15 take your Visa card, name, date of birth, weight, height,
16 what's your problem.

17 You'd say "I have back pain, and I
18 generally take Hydrocodone and Alprazolam," or
19 Hydrocodone, Alprazolam and Soma. At that point in time
15:37:17 20 the order is processed through the Internet and it goes
21 to a doctor somewhere in cyberspace.

22 The doctor might call the patient, but he
23 doesn't examine the patient. He doesn't do anything but
24 look at the order and say, "Okay, I'll approve it."

15:37:38 25 He approves the order, it's sent back to

1 the anchor site, and the anchor site sends it to, like, a
2 pharmacy bulletin board.

3 The pharmacy bulletin board picks it up,
4 and some pharmacist out there, could be in Iowa, could be
15:37:54 5 in California, could be in Florida, they fill the
6 prescription, and within 24, 48, 72 hours, you have your
7 medication.

8 The problem is that whole system was
9 illegal. It was in violation of the law. It was a
15:38:05 10 conspiracy, a drug conspiracy.

11 So you have a patient sitting in
12 Washington, the State of Washington, the doctor's in New
13 Jersey, the pharmacy's in Iowa, and the company that's
14 coordinating all this is in Florida, and they're all
15:38:22 15 getting paid.

16 The doctor would get, like, a prescription
17 cost, so he might get \$15 for every prescription he
18 approves. That doesn't seem like a lot, but if you're
19 approving 30, 40, or 50 prescriptions a day and you're
15:38:36 20 doing it from home, and you really don't need to do
21 anything else but approve, approve, approve, that's a lot
22 of money.

23 A pharmacist gets drug cost plus \$15 for
24 every prescription he fills, and these pharmacies were
15:38:50 25 filling hundreds of prescriptions a day.

1 Q. All right. So in that sense, would that scenario,
2 which I'll bet all parties in this courtroom would say is
3 an atrocious problem, how do the distributors have some
4 measure of responsibility to try to stop that from
15:39:06 5 happening?

6 A. During that time period, and I use this all the
7 time as an example for how a suspicious order would be
8 identified, if these were all brick and mortar pharmacies
9 that were operating outside of the law, if you've got a
15:39:23 10 pharmacy and you're a distributor, and your pharmacy was
11 ordering -- this pharmacy was ordering 5,000 tablets a
12 month for the last two years, and then all of a sudden
13 the pharmacy orders 20,000, and then the next month it
14 orders 40,000, and the next month it orders a hundred
15:39:42 15 thousand Hydrocodone 10 milligram tablets, and then it
16 also starts ordering 20, 30, 40,000 Alprazolam tablets
17 per month, that's suspicious because you had a pattern of
18 purchase, and all of a sudden you started increasing for
19 no apparent reason.

15:40:01 20 That's a suspicious order. That's an order
21 that needs to be investigated through due diligence to
22 determine what was going on.

23 Q. All right. Now, you've got that distributor
24 concern with rogue Internet pharmacies?

15:40:25 25 A. Yes.

1 Q. In this case we've got four defendants who weren't
2 rogue Internet pharmacies per se, but were brick and
3 mortar, or grocery store in one circumstance --

4 A. Yes, sir.

15:40:38 5 Q. -- pharmacies, but they also distributed to --

6 THE COURT: Hold it. There was an
7 objection.

8 MR. MAJORAS: Objection.

9 "Per se" is argumentative.

15:40:47 10 MR. LANIER: Well --

11 THE COURT: Overruled.

12 BY MR. LANIER:

13 Q. But they also distributed to themselves.

14 Here's the question.

15:40:53 15 Is there a requirement for those
16 distributors to maintain a system if they're just
17 distributing to themselves?

18 A. Of course, yes. Absolutely.

19 Q. Why would that be relevant as compared to an
15:41:08 20 Internet, rogue Internet pharmacy?

21 A. Because again, it's not just Internet.

22 I used Internet as an example because
23 that's a pretty straightforward example, but it's any
24 type of diversion.

15:41:20 25 So a brick and mortar pharmacy that's not

1 involved in Internet trafficking can still have anomalies
2 in their ordering patterns because there might be a bad
3 doctor or a bad clinic in that area.

4 Same concept. You start and you're a
15:41:37 5 normal pharmacy and everything's going fine, and you
6 might be ordering five or 10,000 tablets of Hydrocodone
7 or Oxycodone or whatever, and then all of a sudden you
8 start jumping up 15, 30, 40,000, and pretty soon at the
9 end of the year you're up to, you know, 45,000 tablets a
15:41:56 10 month, when you started a few months back at 5,000
11 tablets.

12 And that's an anomaly in the ordering
13 pattern that has to be investigated because obviously
14 there's a bad doctor out there, or a bad clinic or a bad
15:42:12 15 prescriber that's prescribing drugs that -- in quantities
16 that should trigger some type of investigation at that
17 distributor level.

18 Q. In that regard, sir, did you find a time where you
19 wrote letters to the distributors in the United States
15:42:34 20 and talked in those letters about their responsibilities?

21 A. Yes, sir, I did, in 2006 and 2007.

22 Q. All right. So what I'd like to do is look at your
23 letters in 2006 and 2007.

24 First of all, let's start, can you tell the
15:42:57 25 jury why you wrote these letters?

1 A. In 2006 and 2007, in addition to the -- we had a
2 serious, a serious opioid problem. We were seeing opioid
3 prescriptions on the rise. We were seeing our overdose
4 deaths increasing. We were seeing the amount of
15:43:20 5 addiction increasing. We were seeing the amount of ER
6 visits due to drugs increasing. And we needed to do
7 something, we needed to light a fire under the industry
8 to make sure that they understand what's going on.

9 So we sent letters to basically remind them
15:43:40 10 of what their role was in this distribution chain, and
11 also what the requirements were under the law to protect
12 the drugs' movement.

13 Q. I've got a sample letter of the ones that you sent
14 out or that were sent out from the Department of Justice
15:43:59 15 through your name.

16 It's Plaintiffs' Exhibit 10101, if we could
17 please give those to the other side.

18 This is one of the distributor letters that
19 you sent in 2006 to the CVS Indiana, Limited Liability
15:44:25 20 Company.

21 Do you see this?

22 A. Yes, sir.

23 Q. Do you recognize this letter?

24 A. Yes, sir.

15:44:33 25 Q. Is this a letter that -- I think it's about four

1 pages.

2 Did you sign this letter?

3 A. Yes, sir.

4 Q. Did you write this letter?

15:44:42 5 A. I drafted -- I drafted the letter, and it was
6 changed.

7 I drafted the letter. We -- at DEA, we
8 have a system where everybody gets to look at the letter
9 and decide, you know -- I make the final decision on the
15:44:59 10 letter.

11 Q. All right. And I want to have you explain some
12 parts of this letter to the jury, please.

13 A. Sure.

14 Q. You began by saying, "This letter is being sent to
15:45:10 15 every commercial entity in the United States registered
16 with the Drug Enforcement Administration to distribute
17 controlled substances."

18 What did you mean? What were you doing?

19 A. We sent this letter to everybody who has a
15:45:23 20 distribution component within their system.

21 So a manufacturer would get the letter
22 because they're distributors under the Controlled
23 Substances Act.

24 A distributor would get the letter because
15:45:33 25 they're distributors as well.

1 Like a pharmacy chain would get the letter
2 because they are -- they could be self-distributing or
3 they have their own distribution system, they wouldn't
4 necessarily go to a larger distributor like one of the
15:45:48 5 big three.

6 Q. You continue to say -- wait, like one of the big
7 three.

8 Tell the jury what big three means?

9 A. The big three would be AmerisourceBergen, Cardinal,
15:46:02 10 and McKesson.

11 Q. All right. Now, you continue to say, "The purpose
12 of this letter is to reiterate the responsibility of
13 controlled substance distributors in view of the
14 prescription drug abuse problem our nation currently
15:46:18 15 faces."

16 What I'd like you to do is explain why you
17 use this word "Reiterate" here.

18 A. Well, we were just repeating what we said
19 previously during face-to-face meetings or during, you
15:46:35 20 know, inspections, just reminding them what their
21 responsibilities are.

22 It's very clear within the Controlled
23 Substances Act, but we just wanted to tweak them and tell
24 them, you know, remember, this is what your
15:46:49 25 responsibility is.

1 Q. In other words, were you coming up with new
2 responsibilities here?

3 A. No, sir.

4 Q. How long had these responsibilities been in place?

15:47:04 5 A. Since around 1970.

6 Q. The next paragraph you said, "As each of you is
7 undoubtedly aware, the abuse (none medical use) of
8 controlled prescription drugs is a serious and growing
9 health problem in this country."

15:47:30 10 Do you see that (nonmedical use)?

11 A. Yes, sir.

12 Q. So when you wrote this, not just to CVS but to all
13 commercial entities that were distributors, what did you
14 assume they knew was already a problem?

15:47:50 15 A. That -- that the controlled substances,
16 specifically opioids, were basically running through the
17 country, ravaging towns and cities, and that we had to
18 try and put an end to it.

19 Q. All right. You continue to say that, "The CSA,"
15:48:14 20 and that's the Controlled Substances Act?

21 A. Yes, sir.

22 Q. "The CSA was designed by Congress to combat
23 diversion by providing for a closed system of drug
24 distribution."

15:48:28 25 What were you talking about there on a

1 closed system?

2 A. Again, we were trying to get across the fact that
3 the Congressional -- the architecture for the Controlled
4 Substances Act was a system that would prevent drug
15:48:44 5 diversion, prevent -- help prevent addiction, these drugs
6 getting out into the market -- into the illegitimate
7 market, the illegal market, and hurting people.

8 So that was the basis of that.

9 Congress created the infrastructure for the
15:48:58 10 Controlled Substances Act and the closed system.

11 Q. All right. You go on to say that, "The
12 distributors are, of course, one of the key components of
13 the distribution chain. If the closed system is to
14 function properly as Congress envisioned, distributors
15:49:21 15 must be vigilant in deciding whether a prospective
16 customer can be trusted to deliver controlled substances
17 only for lawful purposes."

18 Explain what you meant, please.

19 A. What Congress expected from the Drug Enforcement
15:49:40 20 Administration through the Controlled Substances Act was
21 that we would oversee this system that would stop the
22 movement of controlled substances from the legitimate
23 market to illicit market.

24 And we, in this -- and this system, since
15:49:57 25 we were talking about distributors and distribution, we

1 wanted to make sure that distributors understood that
2 they had to be vigilant, because at that distribution
3 level, at that level where they're supplying pharmacies,
4 they see the whole field, and they could stop diversion
15:50:14 5 from occurring just by employing the requirements that
6 are in the regulations.

7 Q. Was it only the distributors who had that
8 responsibility?

9 A. No, sir.

15:50:27 10 Q. So if we continue to work through your letter, you
11 have on the second page this paragraph that starts out,
12 "DEA recognizes."

13 "DEA recognizes that the overwhelming
14 majority of registered distributors act lawfully and take
15:50:46 15 appropriate measures to prevent diversion. Moreover, all
16 registrants, manufacturers, distributors, pharmacies, and
17 practitioners, share responsibility for maintaining
18 safeguards against diversion."

19 Did I read that correctly?

15:51:04 20 A. Yes, sir.

21 Q. What is your point behind the fact that all
22 registrants, including pharmacies, share a
23 responsibility?

24 A. Because every entity, every registrant within that
15:51:20 25 distribution chain, has certain obligations under the

1 Act.

2 Under the regulations, they all must
3 prevent or they all have to have practices in place to
4 prevent diversion.

15:51:33 5 However, they all have their own set of
6 requirements for preventing diversion, and that's why
7 it's not just one entity, it's just not one level.

8 If they're all doing what they're required
9 to do, then it would minimize diversion considerably.
15:51:55 10 But if one person breaks down in that system, you have
11 diversion. And depending on how quickly it could be
12 discovered, you can have a lot of diversion, a great
13 amount of diversion.

14 Q. In this regard, for these distributors to properly
15:52:12 15 do their job, you've said they need to maintain a system
16 to identify and report a suspicious order.

17 Does the DEA tell them how to do that?

18 A. No, sir.

19 It's -- it's a business decision, a
15:52:29 20 business practice. They know their customers, and they
21 know exactly what they need to meet the requirements of
22 this particular provision within the regulations.

23 Q. So does everyone have to do it the exact same way?

24 A. No, sir.

15:52:50 25 Q. But do distributors have to have a program in

1 place?

2 A. Yes, they do. Absolutely.

3 Q. And does that system need to properly identify and
4 report a suspicious order?

15:53:02 5 A. Yes, it does.

6 That's a requirement under the regulations.

7 Q. Whether it's distributing to the Internet or
8 distributing to brick and mortar?

9 A. Doesn't matter.

15:53:12 10 Q. All right.

11 A. If they've got a registration and they're
12 distributing, it's all the same.

13 Q. Now, in addition to this letter in 2006 -- by the
14 way, I think the evidence is going to indicate that Giant
15 Eagle was not distributing in 2006 when you sent this.

16 Do you know anything about -- I don't even
17 know that you know the facts of our case.

18 Do you know anything about that?

19 A. No, sir.

15:53:38 20 Q. All right. Were these letters also posted anywhere
21 where people who started distributing later could get
22 them?

23 A. I don't know if they're posted now, but I believe
24 they were posted years ago, yes.

15:53:55 25 Q. And in that regard, let's look at a second letter

1 that you sent in 2007. It's Plaintiffs' Exhibit 36 is
2 one that I'll use as a sample.

3 Let me make sure counsel get a copy.

4 A. Thank you.

15:54:28 5 Q. Do you have Plaintiffs' Exhibit 36 in front of you?

6 A. Yes, sir, I do.

7 Q. This is a -- we pulled one that you had sent to
8 Walgreen's.

9 Do you see this?

15:54:38 10 A. Yes, sir.

11 Q. December 27th, 2007.

12 Is that your signature at the end?

13 A. Yes, sir, it is.

14 Q. Why did you write a second letter a year later?

15:54:55 15 A. Because we were still seeing issues within the
16 supply chain regarding diversion, and we again wanted to
17 send a letter out reminding them again what their
18 obligations were.

19 Q. And if the jury were to take the time or we were to
15:55:20 20 take the time to read through this letter, do you say
21 anything new or different than you did the year before,
22 to the best of your memory, recognizing this was 14 years
23 ago?

24 A. One of the things I remember about this letter was
15:55:37 25 we had a final order that was -- that was handed down

1 from the DEA Administrator and the Administrative Law
2 Judge at DEA on a case called Southwood Pharmaceuticals.

3 And we directed them to that particular
4 case so they -- to understand what their requirements
15:55:57 5 were under the Act.

6 Southwood was a revocation action where we
7 removed the license of that particular manufacturer
8 because they were not complying with the Controlled
9 Substances Act.

15:56:11 10 Q. All right. What I'd like to do now is -- and we're
11 almost through with this stuff, but I'd like to try to
12 make sure that we're clear.

13 On the closed system, you've just talked
14 about the distributors.

15:56:28 15 Now, I want to talk about the dispensers
16 and their obligations, the pharmacies.

17 Okay?

18 A. Yes, sir.

19 MR. LANIER: Your Honor, I know we have not
15:56:36 20 yet --

21 THE COURT: Yeah, I was going to suggest if
22 you're -- this may be a good time to take our
23 mid-afternoon break.

24 Ladies and gentlemen, we'll take 15
15:56:44 25 minutes, and then continue with Mr. Rannazzisi.

1 (Jury out.)

2 (Recess taken.)

3 (Jury in.)

4 THE COURT: Okay. Please be seated.

16:16:02 5 Mr. Lanier, you may continue.

6 Mr. Rannazzisi, you're still under oath.

7 THE WITNESS: Thank you.

8 BY MR. LANIER:

9 Q. All right. Mr. Rannazzisi, before that break we
16:16:09 10 were in the thrilling world of distributors.

11 It occurs to me that there are a couple of
12 questions that I failed to ask you that I need to do
13 about the system itself.

14 I think you've told us that each defendant
16:16:27 15 in this case, but any distributor that's a distributor is
16 required to have a Suspicious Order Monitoring system.

17 Can you tell us the abbreviation for that?

18 A. SOM, S-O-M.

19 Q. A SOM program, right?

16:16:40 20 A. Yes.

21 Q. Now, does it have to identify -- is it required to
22 identify orders of unusual size, quantity or deviating
23 from a normal pattern?

24 A. Yes. It's required.

16:16:57 25 That's exactly what it's supposed to be

1 doing, and that's not all-inclusive.

2 Those are just examples.

3 Q. So that and more?

4 A. Yes.

16:17:11 5 Q. You gave us an example of unusual size or quantity.

6 I don't remember which one. But can you
7 give us an example of deviating from a normal pattern?

8 A. Well, there's so many different -- you know, a
9 switch in drugs, where a pharmacy might be ordering a
16:17:30 10 certain Oxycodone 5 milligram is the normal dosing that
11 they're ordering, and they're ordering a certain
12 quantity, and all of a sudden it shifts and they no
13 longer are ordering Oxy 5 anymore, they're ordering Oxy
14 10 or Oxy 15.

16:17:48 15 There's a dramatic shift and no explanation
16 for why that shifted. What happened to all those
17 patients that were on Oxy 5?

18 A perfect -- another perfect example was
19 back in 2010, OxyContin, which was a sustained release,
16:18:07 20 modified release Oxycodone product, went to what they
21 call abuse deterrent formulation.

22 And what we started seeing was pharmacies
23 that were ordering that drug at a certain level, in 2010
24 they started to plummet. I mean, there was almost no
16:18:24 25 orders, but we saw Oxycodone 30 milligram tablets go on

1 the rise.

2 Oxycodone 30 milligram tablets are
3 immediate release single entity product, so there's no
4 explanation.

16:18:39 5 If OxyContin has been used appropriately
6 for so many years, why are the numbers of OxyContin
7 plummeting and why are the Oxycodone 30 milligram tablets
8 going up? That's something that's deviation from the
9 normal pattern, that's something that they should be
16:18:56 10 looking at.

11 Q. All right. I've got size, quantity.

12 Am I missing frequency? Is frequency one
13 of these?

14 A. Yes.

16:19:04 15 Q. Explain frequency.

16 A. So a pharmacy might be ordering once or twice a
17 week. Once a week, twice a week. And all of a sudden
18 they're ordering three times a week, four times a week,
19 maybe twice a day. That's -- that's an unusual
16:19:25 20 frequency.

21 It had a pattern of ordering once or twice
22 a week, and now they're up to three or four times a week,
23 or maybe twice a day.

24 Q. All right. Before I leave this subject, let me ask
16:19:37 25 you this.

1 Can a distributor, whether a defendant or
2 another distributor, ship -- if their system is
3 triggered, can they ship the drug before their due
4 diligence clears the order?

16:19:54 5 A. No, sir, they cannot.

6 Q. Can you explain what that means?

7 A. Well, if -- if an order is deemed to be suspicious
8 by whatever system you're using, if it's a suspicious
9 order, then they have to investigate the order to either
16:20:13 10 resolve the suspicions, or not send the order and report
11 it.

12 If you just send an order downstream even
13 though there's a -- something suspicious about that
14 order, some nature that's suspicious about that order,
16:20:32 15 you're not maintaining effective controls against
16 diversion, which is a requirement both under the statute
17 and the regulations.

18 Q. All right. And then the last question on the
19 system.

16:20:42 20 What is their reporting duty? They being
21 the distributors, either the defendants in this case, or
22 another distributor.

23 A. The distributors must report a suspicious order
24 when it's discovered to the local DEA office.

16:20:59 25 Q. Is that important?

1 A. Yes, sir, it is.

2 Q. Why?

3 A. Because those orders, when received, are looked at.

4 It kind of gives us a pointer system of

16:21:13 5 maybe there's a problem with a certain pharmacy or

6 certain clinic that we need to look at closer.

7 Q. Okay. As we continue to work on explaining the

8 DEA, and working through the closed system, you've talked

9 about the closed system itself, you've talked about the

16:21:30 10 distributors.

11 Now, I'd like you to talk about the DEA's

12 perspective on the obligations of the pharmacies. Okay?

13 And in that regard, let's start with what

14 -- the pharmacies are considered dispensers, is that what

16:21:52 15 they are?

16 A. Yes. They have a dispensing function, that's what

17 they do.

18 Q. And as dispensers, what is the root obligation the

19 DEA believes exists for the behavior of dispensers on

16:22:11 20 opioids, Schedule II drugs?

21 A. Well, on any controlled substance prescription, be

22 it an opioid or any other Schedule II, III, IV or V

23 prescription, when a pharmacist evaluates a prescription,

24 a pharmacist receives a prescription, he must ensure that

16:22:33 25 prescription is issued for a legitimate medical purpose

1 in the usual course of professional practice.

2 That's a corresponding responsibility that
3 a doctor also has. The doctor has a responsibility to
4 prescribe for a legitimate medical purpose in the usual
16:22:50 5 course of professional practice.

6 If they're not doing that, they're in
7 violation of the Controlled Substances Act.

8 A corresponding responsibility exists with
9 the pharmacist to ensure that that prescription is valid
16:23:03 10 and effective; that it contains all the elements
11 and -- elements of a prescription, but also that when
12 that prescription was issued, it was for a legitimate
13 medical purpose.

14 If --

16:23:19 15 Q. I don't mean to interrupt.

16 A. Go ahead.

17 Q. I was going to put the law up here, 1306.04. The
18 jury saw this with the last witness, but I'd like for you
19 from the DEA's perspective, as you understood it when you
16:23:30 20 were there, to speak about this language.

21 "A prescription for a controlled substance
22 to be effective must be issued for a legitimate medical
23 purpose by an individual practitioner acting in the usual
24 course of his professional practice."

16:23:46 25 First of all, that sexist. It could be a

1 she, couldn't it?

2 A. Yes, sir.

3 Q. Did you write that?

4 A. No, sir. That was written before I -- way before I
16:23:56 5 was involved.

6 Q. All right. So in the usual course of his or her
7 professional practice.

8 Explain, first of all, this is an
9 individual practitioner. What do we commonly call them?

16:24:13 10 A. Doctor, dentist, nurse practitioner, physician's
11 assistant, podiatrist. It depends on what type of doctor
12 it is or what your discipline is.

13 Q. Okay. "The responsibility for the proper
14 prescribing and dispensing of controlled substances is
16:24:36 15 upon the prescribing practitioner," again, is that
16 doctor, dentist, nurse practitioner, et cetera?

17 A. Yes.

18 Q. "But a corresponding responsibility rests with the
19 pharmacist who fills the prescription."

16:24:55 20 That phrase "Corresponding responsibility,"
21 is that what you're talking about?

22 A. Yes.

23 Q. And what, from the DEA's perspective, does that
24 entail for the pharmacist?

16:25:16 25 What is that corresponding responsibility?

1 And for the pharmacy, I should say.

2 A. When -- when a pharmacist is presented with a
3 prescription, some prescriptions are presented with what
4 we term red flags.

16:25:31 5 Red flags are identifiers for a pharmacist
6 that there may be a problem with a prescription, and
7 there's a number of red flags.

8 It's the pharmacist's responsibility to
9 resolve those red flags before they dispense the
16:25:48 10 medication. If they can't resolve the red flags, they
11 cannot dispense the medication.

12 That's what corresponding responsibility
13 is. It's a check of the doctor. It's a check to make
14 sure that that doctor is not doing something that could
16:26:03 15 potentially harm the patient.

16 And that pharmacist, who's a professional,
17 has the exact same requirements to make sure that the
18 patient is not being harmed by the drug therapy that he's
19 about ready to dispense.

16:26:18 20 So if the pharmacist cannot resolve those
21 red flags that are in the prescription, or within the
22 prescription, then he can't fill that prescription.

23 Q. In that regard, the next thing I'd like to talk to
24 you about is the difference between the pharmacy and that
16:26:34 25 obligation, and the pharmacist, that obligation.

1 What is the difference between them from
2 the DEA's perception of the law?

3 A. The pharmacy is the DEA registrant.

4 The pharmacy is the responsible party.

16:26:55 5 The pharmacist can't practice without a
6 pharmacy registration or a hospital registration. All he
7 is is a professional that has a license in the state to
8 practice pharmacy, but he needs somewhere to practice.

9 The practice location, that, wherever that
16:27:12 10 practice location is, is the pharmacy, and that is the
11 entity that's registered.

12 So the pharmacist conducts the business of
13 the pharmacy that's registered.

14 Q. So when the statute talks about -- I want to make
16:27:29 15 sure I get this right -- the pharmacy, you said, is the
16 registrant and responsible accordingly?

17 A. Yes.

18 Q. The pharmacist conducts the business of the
19 pharmacy?

16:27:37 20 A. Yes.

21 Q. So who needs to supply the tools for this work?

22 A. Well, the pharmacy would -- would be responsible
23 for supplying the drugs, the computer systems, the
24 reference material, all of the things a pharmacy is
16:28:04 25 required to have to operate appropriately.

1 And the pharmacist, he uses those tools to
2 practice pharmacy, to ensure that the patients --

3 Q. All right. But when the statute itself says that
4 the corresponding responsibility rests with the
16:28:24 5 pharmacist who fills the prescription, how does the DEA
6 understand that and enforce that in terms of the
7 pharmacy?

8 A. The pharmacist is under that obligation of
9 corresponding responsibility, but he wouldn't be a
16:28:44 10 pharmacist under -- he wouldn't be practicing pharmacy
11 without that pharmacy license.

12 So the pharmacist inevitably is responsible
13 to practice pharmacy, but the pharmacy, the registrant,
14 is ultimately responsible for what that pharmacist does.

16:29:02 15 Remember, the pharmacist would not be
16 practicing if he didn't have a practice location or a DEA
17 registration, which is the pharmacy location.

18 So, therefore, it's ultimately the
19 responsibility of the pharmacy for whatever the
16:29:18 20 pharmacist is doing.

21 Q. And accordingly, we'll talk about tomorrow some of
22 the enforcement actions that you've overseen and entered
23 into with various defendants in the courtroom, but have
24 you entered into those with the pharmacies or the
16:29:36 25 pharmacists, or both?

1 A. Generally both, but I can't do a revocation action
2 on a pharmacist because the pharmacist is not a
3 registrant.

4 Pharmacists could lose his
16:29:52 5 registration -- his ability to practice pharmacy. We
6 could go to the State board and ask the State board to
7 review what he's done and have the State board revoke his
8 pharmacist registration, the ability to practice
9 pharmacy.

16:30:06 10 But in the end, we would take action
11 against the pharmacy and remove their registration,
12 because they're the responsibility party.

13 The pharmacist could also be charged with a
14 crime, because if he's distributing a controlled
16:30:20 15 substance outside that usual course of professional
16 practice and not for legitimate medical purpose, if he's
17 just continuing to send drugs out of the store without
18 performing corresponding responsibility analysis,
19 that's -- there's a crime attached to that.

16:30:37 20 That's illegal distribution.

21 Q. Okay. Now, the next word I'd like you to talk
22 about in terms of dispensers and pharmacies and the views
23 from the DEA is this word "Knowing," and I'll show it to
24 you in the language of the regulation.

16:30:56 25 It says, "The person knowingly filling such

1 a purported prescription, as well as the person issuing
2 it, shall be subject to the penalties provided for
3 violations of the provisions of law related to controlled
4 substances."

16:31:21 5 I'd like you to focus on this word
6 "Knowingly filling" and explain how the DEA sees that
7 understanding in the regulation?

8 MR. DELINSKY: Objection.

9 Legal conclusion, Your Honor.

16:31:36 10 MR. LANIER: I --

11 THE COURT: Well --

12 MR. LANIER: I'm asking how the DEA --

13 THE COURT: Well, you need to rephrase
14 this, during the time he was head of the Bureau.

16:31:46 15 MR. LANIER: Right. I've got it.

16 THE COURT: So sustained as it stands.

17 BY MR. LANIER:

18 Q. Sir, and that's the key, during the time that you
19 were at the DEA and you were control head of the Office
16:32:01 20 of Diversion, explain to us what the DEA understanding
21 was of this language of what it means to knowingly fill
22 such a prescription?

23 MR. DELINSKY: Objection, Your Honor.

24 402. What the DEA believes is --

16:32:17 25 THE COURT: Okay.

1 (Proceedings at side-bar:)

2 THE COURT: All right. I'll still sustain
3 the objection the way it's asked.

4 You can ask him how did he apply it when he
16:32:50 5 was head of the division of control.

6 All right?

7 MR. LANIER: Okay. Got it.

8 (End of side-bar conference.)

9 BY MR. LANIER:

16:33:09 10 Q. So the record is clear, sir, let me ask it this
11 way.

12 How did you apply that language of
13 "Knowing" when you had the leadership roles you had in
14 the DEA?

16:33:22 15 A. During my time at the DEA, it was we looked at it
16 as knowing or having reason to know.

17 And that's been discussed in DEA cases, in
18 DEA final orders, since 2009 -- or, I'm sorry, take that
19 back, since 1990.

16:33:42 20 The -- when you're presented with red
21 flags, you can't turn a blind eye to those red flags.
22 You have to analyze the prescription, look at the red
23 flags, and resolve them.

24 You can't just take a blind eye and say, "I
16:34:02 25 don't see anything" and send the prescription out.

1 You're not doing the patient any good. You're not doing
2 the -- your practice any good. And you could potentially
3 hurt somebody.

4 So you can't turn a blind eye. You
16:34:15 5 must -- you must resolve those red flags. You can't turn
6 a blind eye to the red flags and, therefore, it's reason
7 to know as well as know.

8 Q. All right. Mr. Rannazzisi, another term that you
9 keep using that I'd like you to discuss for a moment is
16:34:32 10 that term "Red flags."

11 What do you mean when you use the term "Red
12 flags"? And when you use it, I'm talking about as your
13 role in DEA?

14 A. Again, during my time at DEA, red flags were
16:34:54 15 indicators to the pharmacist there could be a potential
16 problem with the prescription.

17 So it could be that the patient is seeing a
18 doctor that's 50 miles away from your pharmacy and he
19 lives 30 miles away from your pharmacy, but he's showing
16:35:12 20 up at your pharmacy to get the prescription filled.

21 It could be that you're on the largest, the
22 highest dose of the highest single entity Oxycodone
23 product in large quantities with a drug like Alprazolam
24 and Carisoprodol.

16:35:30 25 It could be that you're traveling in pairs

1 or three people who are showing up at the same pharmacy
2 with the same prescriptions from the same doctor who's
3 located quite a bit away. Same people at the same
4 address who are showing up with the same prescriptions.

16:35:47 5 There's so many different things that are,
6 quote, unquote, red flags that the pharmacists are
7 trained to look at, they're trained to see these
8 potential indicators of diversion, and they have to
9 resolve those.

16:36:04 10 Q. Now, in that regard, I've put down the four
11 illustrations you gave, but I added the note "So many
12 more" because I think that's what you were saying just
13 now, but I want to make sure I've got that accurate.

14 A. There's a ton. I just gave you four off the top of
16:36:21 15 my head, but there's many different red flags in
16 different circumstances.

17 Q. Would you expect pharmacies that deal in this stuff
18 to be conversant with that language I'll use of red
19 flags?

16:36:35 20 A. Yes.

21 Q. Now, the next thing I'd like you to talk about is
22 something that is called -- I'm calling it, I should say,
23 percentage testing.

24 Let me tell you what I'm talking about.

16:36:56 25 In this case, the lawyers for the

1 pharmacies have said that the DEA has a test, and as long
2 as less than 20 percent of the drugs, prescriptions being
3 filled, are opiates, then it doesn't trigger the DEA
4 test.

16:37:18 5 My question to you is, sir, does the DEA,
6 if you're below 20 percent fill on opioids, does the DEA
7 at that point say you can ignore red flags, it's all
8 fine?

9 A. No.

16:37:36 10 Q. Can you put any sense to this at all for us so that
11 we can understand the perspective that you bring from
12 your job at the DEA?

13 MR. MAJORAS: Objection. Leading.

14 Opinion testimony.

16:37:49 15 THE COURT: Overruled.

16 A. During my tenure at DEA we looked at percentages,
17 but that was not -- that was not the end-all.

18 You could have a pharmacy that has a
19 smaller percentage of opioid -- a larger percentage of
16:38:10 20 opioid-to-noncontrolled drug purchases or dispensing, and
21 that pharmacy might be fine; but you also could have a
22 pharmacy that has a very small percentage, 12 percent,
23 but when you look at their opioids, every opiate that's
24 going out the door is an Oxycodone 30 milligram tablet.

16:38:31 25 Well, that doesn't make any sense.

1 Okay. So the percentage is there. It's,
2 again, it's a pointer, it's a trigger, it's an indicator,
3 but it's not necessarily the end-all. And you can't say,
4 well, if it's less than 20, we don't have to worry about
16:38:49 5 it, because that's not how the system should be set up.

6 Q. Then if I can wedge it in, the last thing I need to
7 talk to you about is the need to document the resolution
8 of red flags.

9 Can you talk to us about that, please?

16:39:07 10 A. Yes.

11 Q. Well, let me take a time out and take a step back,
12 and go back to red flags.

13 If a prescription for opiates presents with
14 red flags, what, according to the DEA while you were
16:39:26 15 there, what should the pharmacist do?

16 A. During my tenure, we expected the pharmacists to
17 resolve those flags.

18 That means look at each individual red flag
19 and try and determine why that flag is there and can it
16:39:50 20 be resolved, can -- "Is there a reason why this guy's 50
21 miles away from home with a doctor 20 miles the other way
22 going to your pharmacy in Ohio," or wherever.

23 "Is there a reason why this particular
24 patient, who you've never seen before, is getting
16:40:13 25 Oxycodone 30 milligram tablets in addition to Alprazolam

1 or Xanax, and another drug like Carisoprodol or
2 Flexeril?"

3 You know, it may mean making a phone call
4 to the doctor, it probably is an initial phone call to
16:40:32 5 the doctor saying, "We're just curious, what are you
6 treating this patient for, why is he on the highest dose
7 Oxycodone? Why is he on two opioids? Why is he coming
8 to my pharmacy? And what's your specialty? It doesn't
9 say on the prescription. Is this a cancer patient, an
16:40:48 10 oncology patient?"

11 That's how a pharmacist would resolve.
12 It's not just the phone call, though. He's got to use
13 his professional judgment.

14 So if I pick up a phone and call a doctor
16:40:58 15 and say, "Hey, Doc, I'm just curious, I don't know you or
16 your practice, but I've got this prescription in here for
17 Oxycodone 30 milligram tablets, 180, and Alprazolam.
18 Just curious, what are you treating the patient for?"

19 And if his response is, "Oh, don't worry
16:41:14 20 about it, it's good, just go ahead and fill it," that's
21 not enough.

22 Just because a doctor tells me that the
23 prescription's okay is not enough. You've got to do a
24 little further digging because, remember, that's your
16:41:26 25 patient just like it's the doctor's patient. That's what

1 corresponding responsibility is all about.

2 We're trying to prevent that patient from
3 getting harmed. And if you don't take that step, if you
4 just say, you know, "Doctor, that's all right, as long as
16:41:40 5 you say it's okay, I'm going to fill it," well, you're
6 not doing corresponding responsibility.

7 And we have case upon case upon case where
8 that's occurred, and people were harmed, and people died.

9 Q. All right. In this regard, now, with that
16:41:58 10 understanding of red flags, talk to us about
11 documentation and what it needs to be, please.

12 A. Whenever a pharmacist --

13 MR. DELINSKY: Objection, Your Honor.

14 There's no qualification to that question.

16:42:13 15 THE COURT: All right. You're going to
16 have to go through a few steps, Mr. Lanier.

17 BY MR. LANIER:

18 Q. All right. Are you still a licensed pharmacist?

19 A. Yes, sir.

16:42:22 20 Q. Do you understand the obligations of a pharmacist
21 as a pharmacist?

22 A. Yes, sir.

23 Q. Are you still someone who carries in your brain the
24 memories of what you did when you worked for the DEA?

16:42:34 25 A. Yes, sir.

1 Q. Have you given lectures for the DEA that concern
2 the issues, including documentation?

3 A. Yes, sir.

4 Q. Have you given lectures not just on behalf of the
16:42:49 5 DEA, but to other groups, where you've spoken about the
6 need to document?

7 A. Yes, sir.

8 Pharmacy Boards and Medical Boards.

9 Q. And are you up-to-date with the Pharmacy Boards and
16:43:01 10 the Medical Boards and the standards of professional
11 conduct when it comes to documentation?

12 A. I believe I am, yes.

13 MR. LANIER: With that foundation, Your
14 Honor, I'd like to ask him his understanding of
16:43:13 15 documentation?

16 THE COURT: Okay.

17 MR. DELINSKY: Objection.

18 Calls for a legal conclusion, Your Honor.

19 THE COURT: Overruled.

16:43:17 20 BY MR. LANIER:

21 Q. So, please, with that background as your
22 foundation, would you tell the jury your testimony about
23 what documentation needs to be? And then I'll ask you
24 another question about why.

16:43:32 25 But what does it need to be, first?

1 A. There has to be some documentation that you -- if
2 you call the doctor, there's got to be documentation
3 somewhere, either in a patient profile or on the
4 prescription, that you called the doctor and why you
16:43:49 5 resolved those red flags.

6 That's -- during my time at DEA, we
7 expected that. When we pulled prescriptions, that's what
8 we were looking for.

9 Q. Okay.

16:44:01 10 A. That doc doesn't necessarily have to be on the
11 prescription. It could be in a patient profile. It
12 could be in some type of medium within a computer, but
13 there's got to be something there.

14 It's a professional practice standard.

16:44:18 15 Q. And why is that, from your perspective and your
16 foundation, why is that important?

17 A. Because again, you're establishing whether you
18 filled the prescription or you didn't fill the
19 prescription, and why.

16:44:36 20 This might come back a month from now, this
21 prescription might come back two months from now, and
22 it's in the patient profile, and the other pharmacists,
23 if you're working with other pharmacists, could see what
24 you did and build on that, try and figure out if there's
16:44:51 25 still a problem with this prescription, even though it

1 was -- the red flags are resolved.

2 But at least you've established some kind
3 of record.

4 The Drug Enforcement Administration doesn't
16:45:00 5 dictate the practice of pharmacy. At least when I was
6 there, we didn't dictate the practice of pharmacy. We
7 actually looked to the Pharmacy Board to determine what
8 the requirements are.

9 And I was taught, and when I did practice,
16:45:16 10 notation on the prescription for what you did, especially
11 when you called a doctor, was imperative, it was
12 important. It was part of your requirements as
13 practicing pharmacy.

14 Q. All right. Now, what I'd like to do, the last
16:45:31 15 thing I want to do under the education stop or explain
16 the DEA, is I would like you to explain enforcement
17 proceedings and how they came about, and what they
18 basically are.

19 And in regards to this, I want you to do it
16:45:55 20 without referencing any of these defendants at this point
21 in time. So let's just talk in general about how
22 enforcement proceedings came about.

23 Okay?

24 A. Okay.

16:46:06 25 Q. All right. Stage one of enforcement proceedings,

1 where does it start?

2 A. We'll receive a tip or we will be conducting an
3 investigation or inspection, and we'll develop
4 information from that investigation or that inspection
16:46:29 5 that shows violations that are at a level that would
6 require us to move forward with an administrative action.

7 Q. All right. Let's stop for a moment.

8 So you'll get a tip. Give us an example of
9 what that might be.

16:46:46 10 A. Could be from a Board of Pharmacy, could be from a
11 doctor, it could be from a pharmacist. Could be from a
12 patient that something happened during that -- that
13 transaction, or something happened with a doctor's
14 prescribing, or something happened with a pharmacist's
16:47:05 15 dispensing that was not right.

16 It could be an inspection, we're in a
17 facility or in a pharmacy, and we're inspecting
18 something, and we're seeing things that we shouldn't be
19 seeing.

16:47:18 20 Recordkeeping, security, all those things
21 could trigger an administrative action.

22 Q. All right. So those trigger an administrative
23 action.

24 Explain what happens when an administrative
16:47:33 25 action gets triggered.

1 A. We review the evidence from whatever that tip or
2 investigation, subsequent investigation is.

3 And we make a decision, the agency makes a
4 decision on how to proceed.

16:47:54 5 Q. How is the evidence gathered?

6 A. Through things -- we could be gathering that
7 evidence on a notice of inspection.

8 We could gather it on an administrative
9 inspection warrant, which is like a search warrant, but
16:48:10 10 it's for the registrant. It's an administrative action
11 rather than a full-blown search warrant.

12 It could be obtained by subpoena request,
13 but in either case we gather all of this information, we
14 put it together, and we match the information that we
16:48:31 15 received, the information that we developed during the
16 investigation, and we match it to what the regulations
17 say and what the statute says, what you're required to
18 do.

19 And if we find that those regulations and
16:48:45 20 the statute have been violated, and depending on the
21 nature of the violation, we proceed with the
22 administrative action.

23 Q. All right. And then what is the process if you
24 proceed with an administrative action?

16:49:02 25 What does that mean?

1 A. Well, it depends on the violations.

2 If the violations are minor, we might send
3 a letter of reprimand, just a letter basically outlining
4 what your violations are.

16:49:22 5 If they're a little more serious, they
6 might have a field hearing, where you'd appear before the
7 field and -- the Special Agent in Charge in the field,
8 and they'd talk about the violations, and they'd come up
9 with a method of resolving those violations to ensure
16:49:43 10 that diversion doesn't occur.

11 But there are times where we have to
12 proceed in a more forceful administrative action, and
13 that would be an order to show cause.

14 And an order to show cause is basically
16:49:59 15 notice. When we do an order to show cause, it's served
16 on the registrant, and what an order to show cause is,
17 basically here's a notice that you've committed
18 violations that would take you to a level that you
19 must -- you can appear before an Administrative Law
16:50:18 20 Judge.

21 And what an order to show cause does is
22 gives you the opportunity to appear before that Judge, if
23 you wish, and show cause as to why the Government should
24 not revoke your registration or take action against your
16:50:30 25 registration.

1 Q. So this order to show cause, is that a written
2 document?

3 A. It is a written document, yes.

4 Q. Who prepares it, Mr. Rannazzisi?

16:50:50 5 A. When I was with DEA, the -- the document was
6 prepared by, generally, the investigating DI, and then
7 it's provided to an attorney.

8 And the attorney does the review and
9 overall preparation, completion of the preparation,
16:51:14 10 before it's sent up the chain to be reviewed and
11 looked -- and signed.

12 Q. Tell the jury if you -- who all you had on your
13 staff when you were the head.

14 Did you have a lawyer, et cetera?

16:51:27 15 A. I had a -- my staff included a special agent, a
16 senior special agent, a senior diversion investigator,
17 and an attorney that handled both regulatory, regulatory,
18 legislative, and liaison matters.

19 But inevitably, she would look at the order
16:51:55 20 to show cause, the two executives would look at the order
21 to show cause before I saw it.

22 Q. We are going to get to the *Holiday* case tomorrow,
23 hopefully. The *Holiday* case is a written decision.

24 How does this enforcement proceeding
16:52:17 25 section finally produce a written decision?

1 A. If you're the registrant and we take action against
2 your registration through the order to show cause
3 process, you're entitled to due process, to appear before
4 an Administrative Law Judge to hear your case.

16:52:35 5 Once the Government presents evidence and
6 the registrant presents their evidence, the
7 Administrative Law Judge looks at everything and
8 gets -- basically gives a recommended decision to the
9 administrator of the Drug Enforcement Administration.

16:52:54 10 The administrator then looks at the
11 recommended decision, looks at the administrative record,
12 and makes a decision on what should be done with that
13 registrant, be it a revocation, a suspension, maybe a
14 suspension with a removal of certain drug products from
16:53:17 15 their registration, but it's ultimately the Administrator
16 of the Drug Enforcement Administration makes that
17 decision.

18 Q. Now, the jury has also heard about settlement
19 agreements.

16:53:36 20 MR. STOFFELMAYR: Excuse me, Judge.

21 THE COURT: Wait. Hold it.

22 (Proceedings at side-bar:)

23 THE COURT: All right. Is there an
24 objection?

16:53:49 25 MR. STOFFELMAYR: Yeah, Judge. It's Kaspar

1 Stoffelmayr.

2 The witness has said three times,
3 obviously, this is an administrative proceeding before an
4 Administrative Law Judge. It's all internal to the
16:53:58 5 agency. And Mr. Lanier keeps writing down "Judge" which
6 leaves the impression it's a Judge like yourself in
7 court.

8 MR. LANIER: I'm glad to make that change,
9 Judge.

16:54:06 10 THE COURT: "ALJ."

11 MR. LANIER: Yeah, I'm glad to make that
12 change.

13 (End of side-bar conference.)

14 BY MR. LANIER:

16:54:19 15 Q. For clarity sake, I wrote "Appear before Judge" and
16 I wrote "Judge renders a decision."

17 You called that Judge an Administrative Law
18 Judge, is that right?

19 A. Yes, sir, an ALJ, an Administrative Law Judge.

16:54:34 20 Q. An ALJ is an Administrative Law Judge.

21 Can you explain how that's different than,
22 for example, His Honor, Judge Polster?

23 A. Judge Polster's a District Court Judge, an Article
24 III Judge, part of the Judiciary branch, judicial branch
16:54:58 25 of the three-branch system of Government.

1 An Administrative Law Judge is not a
2 Senate-confirmed position. An Administrative Law Judge
3 is appointed by the Department of Justice and sits at the
4 agency that he's assigned to to hear cases.

16:55:20 5 Different, he doesn't hear criminal cases.
6 He doesn't hear civil cases.

7 The only thing an Administrative Law Judge
8 does is hear administrative cases regarding DEA
9 registrants.

16:55:32 10 Q. So when we spoke here about appearing before a
11 Judge, you mean an Administrative Law Judge, an ALJ?

12 A. Yes, sir.

13 Q. And when we spoke here about the Judge renders a
14 decision -- well, take a step back.

16:55:47 15 About the Government presenting their
16 evidence, do they present it to a jury, or to the
17 Administrative Law Judge?

18 A. To the Administrative Law Judge, who reviews
19 evidence and makes evidentiary rulings, just like a
16:56:01 20 regular judge does.

21 Q. And -- and by the same token, when the registrants
22 present their evidence, are they presenting it also to
23 the same Administrative Law Judge?

24 A. Yes, they are.

16:56:12 25 Q. And then is that the Judge that renders a decision?

1 A. It's a -- it's a recommended decision.

2 Q. Explain what you mean by a recommended decision.

3 A. The Administrator does not have to take the
4 decision of the ALJ.

16:56:25 5 The Administrator is tasked with coming up
6 with the final order, looking at what the ALJ did,
7 looking at what the administrative record says, and then
8 creating a final order that either does the revocation of
9 the registration or does a suspension, or something less
16:56:48 10 than revocation.

11 But it's -- the ALJ provides a recommended
12 decision or recommended opinion on what happened and
13 what -- what they feel is -- should be done, and the
14 Administrator can take the recommended decision and make
16:57:06 15 it the final order, or they could -- they could modify
16 it, or they could change it.

17 It's up to the ALJ -- the -- it's up to the
18 Administrator. The Administrator sits as the trier of
19 fact.

16:57:20 20 Q. All right. Now, you've walked us through the
21 enforcement proceeding, but I think it would be relevant
22 to also hear about settlement agreements that are entered
23 into between the Department of Justice and various people
24 or entities under the Controlled Substances Act.

16:57:38 25 So can you explain to us, please, how a

1 settlement agreement comes about, back during your
2 tenure?

3 A. During -- during my tenure, a settlement -- so it
4 could happen before the order to show cause is issued or
16:57:58 5 it could happen after the order to show cause is issued.

6 Generally, the Government or the Drug
7 Enforcement Administration and the registrant sits down
8 and they discuss the case, the matter, and if they could
9 come to a reasonable settlement that both parties agree
16:58:22 10 to, then they proceed with the settlement and sign the
11 documents for settlement.

12 Q. Okay. So the settlement agreement, I assume,
13 starts with the same tip or investigation?

14 A. Yeah. It's the same, same concept.

16:58:39 15 It could happen before the order to show
16 cause is issued or it could happen after the order to
17 show cause is issued, but before it goes -- it actually
18 could happen at any time before the final order is issued
19 by the Administrator.

16:58:56 20 Q. So it's fair for me to write down here "Any time
21 before the decision or final order is issued"?

22 A. Yes.

23 Q. Okay. I think that eliminates our material at this
24 stop, and so we've made it through experience, explain
16:59:31 25 DEA, and now it's time to talk about defendant

1 interactions.

2 What I'd like to do on defendant
3 interactions is start out by talking to you about one of
4 your PowerPoints. And I think the best way to go about
16:59:59 5 this is to have you first explain -- I mean, I've got a
6 monster PowerPoint here that's yours. I've got a bunch
7 of them, and it's on card stock, so it's a little
8 thicker.

9 Did you -- tell the jury where these things
17:00:20 10 come from.

11 A. These, these are presentations that we do in the
12 normal course of our -- our day-to-day employment when I
13 was at DEA.

14 So we would create the presentations.

17:00:39 15 Generally I would -- I would come up with how I want the
16 presentation to proceed, and I might create slides, and I
17 would provide them to somebody who's a lot better at
18 PowerPoint than I was.

19 They tweaked the slides, send it back to
17:00:54 20 me. We go back and forth. But any -- those slides and
21 those presentations were done by my office and my
22 immediate staff. We all worked together to create those
23 presentations.

24 Q. And what are these presentations you are making?

17:01:11 25 A. They could be for the regulated community.

1 They could be for continuing education for
2 pharmacists or doctors, professional organizations, law
3 enforcement, community groups, Congress.

4 We've done presentations pretty much for --
17:01:35 5 when I was there we did presentations for pretty much
6 everyone that requested them.

7 Q. And would you travel around the country to give
8 these presentations?

9 A. Yes.

17:01:46 10 Q. Would you give these presentations to pharmacies?

11 A. If -- pharmacists, yes.

12 Q. Would you give these presentations to doctors?

13 A. Yes.

14 And I believe both the pharmacists and the
17:02:01 15 doctors were afforded continuing education to see those
16 presentations.

17 Q. So they would get credit towards their number of
18 hours they have to stay up to snuff, as we would say?

19 A. Yes.

17:02:19 20 Q. Would you give these presentations to national or
21 to state pharmacy boards?

22 A. Yes.

23 Q. In fact, sometimes would you give these
24 presentations in conjunction with state pharmacy boards?

17:02:32 25 A. Yes.

1 Q. Did you give presentations, for example, with one
2 of the Ohio Board of Pharmacy's people?

3 A. Yes. We did pharmacist diversion awareness
4 conferences with the National Association of Boards of
17:02:52 5 Pharmacy, and my department, the person that I presented
6 with regularly was the former President of the Ohio
7 Board of -- Executive Director of the Ohio Board of
8 Pharmacy.

9 Q. And what was that person's name?

17:03:10 10 A. William T. Winsley.

11 Q. William Winsley. And you would co-produce with
12 him? Co-produce -- co-present with him?

13 A. Yes. Just pretty much every presentation that I
14 did, he was with me when we did it.

17:03:34 15 Q. All right. You kind of had PowerPoints that were
16 living, breathing, growing organisms, you said in your
17 deposition.

18 Explain that to the jury so that they
19 understand that there will be slight nuanced differences
17:03:50 20 in your presentations.

21 A. The presentations were created to inform a
22 particular audience about what's going on.

23 So the presentation for a community group
24 is not going to be the same as a presentation for a group
17:04:04 25 of doctors or a group of pharmacists.

1 We also tried to get the most updated
2 information to them when we were out there. So if we
3 knew that a new drug was emerging as a potential drug of
4 abuse, that would be thrown into the presentation.

17:04:17 5 If we saw things that we didn't -- that we
6 haven't seen since the last presentation, or we learned
7 from those pharmacists about something they were seeing,
8 it would be thrown in the next presentation.

9 We use statistics from that particular
17:04:32 10 state where we're operating from, so when we set up the
11 statistical chart, they would see the rise of
12 prescriptions for Hydrocodone or the rise in distribution
13 of Hydrocodone, the rise in distribution of Oxycodone,
14 little anomalies within their state on the distribution
17:04:52 15 of certain drugs.

16 We talked about red flags for pharmacists.
17 We talk about red flags for doctors.

18 So depending on who we talked to, the
19 presentation was molded so they understood what was going
17:05:06 20 on in their little world and how they could help.

21 Q. So when you did these as DEA, I understand that one
22 of the first ones of a certain kind you actually did in
23 Cincinnati, Ohio.

24 Is that right?

17:05:20 25 A. Yes.

1 Q. Can you explain what that one was, that group where
2 you kicked it off in Cincinnati?

3 A. It was -- it was pharmacists.

4 And we invited law enforcement, too. If I
17:05:34 5 remember correctly, and that was back in, I think, 2010
6 or '11, I think it was '11, we wanted to get the
7 pharmacists in a room with some law enforcement people so
8 they could know each other and know the regulatory board,
9 and learn about what was going on at that time, because,
17:05:53 10 remember, '11 was pretty much right almost at the top,
11 height of the pharmaceutical opioid epidemic. I think we
12 peaked at '12.

13 And we were trying to get as much
14 information out as possible.

17:06:08 15 Q. Okay. Now, we need to go for another nine minutes,
16 and I can get into this, but instead I'm going to ask you
17 a side topic for just a moment, and then -- because I
18 want to try to do this in one fell swoop tomorrow.

19 A. Okay.

17:06:23 20 Q. So here's a side topic.

21 In addition to these PowerPoint
22 presentations, I know of at least two other kinds I want
23 you to tell the jury about. Okay?

24 One is you gave a presentation after you
17:06:36 25 left the DEA to the Central Oklahoma -- no, to the

1 Oklahoma State Medical Association as their continuing
2 education program.

3 Can you tell the jury how you're giving
4 presentations now, having left the FDA -- I mean the DEA?

17:06:56 5 MR. MAJORAS: Objection. Relevance.

6 MR. LANIER: Judge, it's dead on relevant.

7 It's --

8 MR. MAJORAS: Oklahoma?

9 MR. LANIER: Yeah. It's not tailored to
17:07:09 10 Oklahoma only.

11 It's --

12 THE COURT: Well, I'm not --

13 MR. LANIER: It's entitled "Who should
14 we" --

17:07:16 15 THE COURT: Let me --

16 (Proceedings at side-bar:)

17 MR. LANIER: Judge, it's entitled "Who
18 should we blame for the opioid epidemic?"

19 He gave this presentation two years ago,
17:07:34 20 October 25th, 2019. He gave it to the Oklahoma State
21 Medical Association. In it, he talks about not only the
22 stuff he did with the DEA, but he specifically talks
23 about the responsibility that pharmacies have. And he
24 was questioned about it in his deposition by Ms. Swift
17:07:55 25 last week and -- or the week before last, and I think

1 it's incredibly relevant.

2 It's a summary of his --

3 THE COURT: Well, I'm going to sustain
4 this.

17:08:04 5 He's not an expert witness, and I don't
6 think you can bring him in just to say who he blames.

7 MR. LANIER: Okay.

8 THE COURT: If you want to establish that
9 somehow -- well, he's not speaking for the DEA in 2020 or
17:08:20 10 '21.

11 MR. LANIER: Okay.

12 THE COURT: So I'm going to sustain -- I'm
13 going to sustain the objection.

14 MR. LANIER: All right. Thank you, Judge.

17:08:26 15 (End of side-bar conference.)

16 BY MR. LANIER:

17 Q. In addition to the presentations that you've done
18 that we've talked about, you've also presented to
19 community groups, is that right?

17:08:46 20 A. Yes, sir, I have.

21 Q. And just to get an idea of that, were you doing
22 that also when you were with the DEA?

23 A. Yes, sir. Yes, sir.

24 Q. And what would your community -- I mean, when we
17:08:59 25 say community groups, what do you mean?

1 A. Different organizations that have, for instance,
2 there's an organization in Michigan that, prior to COVID,
3 used to ask me to come out and speak, Families Against
4 Narcotics.

17:09:17 5 And I would go out and speak to them about
6 what I was seeing now post DEA as a problem, and we'd
7 just give them a presentation just to make sure they're
8 up-to-date on what's going on.

9 Q. Are these presentations something that you took
17:09:38 10 seriously?

11 And by these, I'm especially talking about
12 the ones you did as the DEA.

13 A. Yeah, it was part of our -- we felt that we had to
14 take the information to the regulated community. They
17:09:52 15 needed to see what was going on.

16 And not just distributors and pharmacies,
17 but the doctors as well, and, you know, anybody who would
18 listen, the boards. Anybody that could touch on the
19 problem and maybe make a difference in the problem.
17:10:08 20 That's who we looked at.

21 Q. All right. In that regard, I'd like to begin
22 talking to you about your presentations, and the specific
23 one that I want to direct the attention to, first, is
24 Plaintiffs' Exhibit 15962.

17:10:24 25 If we could hand that out, please, Rachel.

1 Thank you. Thank you, Maria.

2 Is this a pretty standard example of what
3 you would do when you go out as the DEA and give these
4 presentations?

17:11:00 5 A. Yes, sir.

6 Q. And the front page --

7 MR. MAJORAS: Objection.

8 THE COURT: Well --

9 MR. MAJORAS: Relevance in terms of
17:11:16 10 jurisdiction. Hearsay, hearsay within hearsay.

11 THE COURT: Wait.

12 (Proceedings at side-bar:)

13 THE COURT: All right. First, it's not
14 hearsay.

17:11:33 15 He did it. It's his presentation,

16 Mr. Majoras, so --

17 MR. MAJORAS: Your Honor, if I could just
18 on that point, there's hearsay within hearsay if there
19 are documents in this multi -- you know, major thing that
17:11:44 20 purports to state facts. Those are all hearsay as to
21 what those facts are.

22 THE COURT: Not if he's made the
23 presentation. You can cross-examine him on anything he
24 said.

17:11:54 25 MR. MAJORAS: But it doesn't verify the

1 facts, Your Honor.

2 It's what he said out-of-court.

3 THE COURT: It's what he said, so what is
4 the -- what is the relevance of this document?

17:12:04 5 MR. LANIER: The relevance, it basically is
6 from nuts to bolts. He'll talk about the migration map
7 that I used in opening. He'll talk about the problems of
8 diversion, what those problems are, where they come from,
9 what can be done about it. He'll talk about red flags.
17:12:23 10 He'll talk about corresponding responsibility. It's
11 dead-on relevant, it's the case.

12 MR. MAJORAS: Sounds like expert testimony,
13 Your Honor.

14 MR. LANIER: No. It's what he gave as
17:12:31 15 his --

16 THE COURT: Well, yeah, you can't bring him
17 in as an expert on what he concludes about the cause of
18 the opioid epidemic.

19 He can testify about what he did while he
17:12:53 20 was head of the DEA Office of Diversion, but he
21 can't -- he can't -- he's not an expert.

22 I'm concerned about this whole line, and
23 certainly this document. So I'm not saying you can't ask
24 him any questions. Again, you can -- he can testify as
17:13:15 25 to what he did while he was head of that office at DEA

1 and that he made presentations, that's fine.

2 MR. LANIER: Well, Judge, I mean, that he
3 made a presentation in itself is irrelevant if I don't
4 get into the presentation.

17:13:35 5 The issue I've got is, and I know we're at
6 5:15, so maybe we can look at this and I can give you a
7 bench brief of one page or two pages.

8 THE COURT: All right. Well, Mr. Lanier,
9 you can't -- you can't use him as an expert as to the
17:13:50 10 causes of the opioid epidemic.

11 I'm not going to allow that. He can't
12 testify to that.

13 He can testify as to DEA enforcement
14 actions, DEA settlements, but I don't know where this is
17:14:08 15 going, so at the moment I'm going to sustain the
16 objection.

17 MR. LANIER: All right. Can I -- can I
18 reoffer it in the morning, Your Honor, with a clearer
19 presentation of what I want?

17:14:17 20 MR. MAJORAS: I've got other objections,
21 too, Your Honor.

22 THE COURT: Why don't over the evening you
23 discuss this among yourselves and see if you can come to
24 some agreement? If not, I'll have to deal with it
17:14:31 25 tomorrow.

1 MR. MAJORAS: Yes, sir.

2 MR. LANIER: Okay. Thank you.

3 (End of side-bar conference.)

4 THE COURT: All right. Ladies and
17:14:39 5 gentlemen, we're going to break for the evening.

6 It's been a long day, and I appreciate your
7 accommodating my schedule so I could do that
8 naturalization.

9 Usual admonitions apply. Don't, you know,
17:14:53 10 read, view, listen to anything in the media. Do not
11 discuss this case with anyone.

12 And we'll pick up tomorrow at 9:00 a.m.
13 with more testimony from Mr. Rannazzisi.

14 (Jury out.)

17:15:35 15 THE COURT: All right. Everyone can be
16 seated for a minute.

17 And now you can step down, sir. This is a
18 legal discussion I need to have.

19 THE WITNESS: Thank you.

17:15:44 20 THE COURT: All right. I don't have time
21 now to have a protracted discussion on this because I
22 have to teach a class this evening, but see if you can
23 figure out agreeable contours for this.

24 If you can't, again, at the moment I don't
17:16:02 25 understand how this is going to lead to admissible

1 testimony, so see what you can figure out. And if you
2 can't agree, I'll have to deal with it tomorrow morning
3 at 8:45.

4 Also, there were a large number of exhibits
17:16:18 5 that both sides used with Mr. Catizone over the course of
6 two full days almost. I'd like to know, have a list of
7 what exhibits the plaintiffs want to offer, and what, if
8 any, exhibits the defendants want to offer, because,
9 again, the defendants are free to offer documents that
17:16:37 10 were used, and if there's any objection I'll deal with it
11 on the record at some point tomorrow.

12 Okay?

13 MR. DELINSKY: Your Honor.

14 THE COURT: Yes.

17:16:52 15 MR. DELINSKY: I think we're heading into
16 territory tomorrow that could be a little charged on
17 where the line is.

18 MS. FUMERTON: Mr. Delinsky, the witness is
19 still here.

17:17:05 20 THE COURT: Doesn't matter what he hears.
21 I mean, it's not what questions will be asked.

22 MR. DELINSKY: It's fine with me.

23 But where the line is, Your Honor, what's
24 sufficient for notice and what goes beyond notice.

17:17:19 25 In other words, this --

1 THE COURT: Well, this has nothing to do
2 with notice testimony.

3 MR. DELINSKY: Your Honor, I'm talking
4 about the enforcement action in Florida and to what
17:17:30 5 degree of detail, to the extent there's --

6 THE COURT: Well, I know little or nothing
7 about this Florida enforcement action, what documents,
8 what the plaintiffs are planning to get into, so again,
9 you know, a lot of this stuff should have been presented
17:17:41 10 to me beforehand.

11 If we have to take up time after 9:00
12 o'clock, it's charged to both sides.

13 MR. DELINSKY: Okay.

14 THE COURT: Each will be charged with it.
17:17:50 15 I mean, obviously if it's something I've
16 got to deal with it, I'm the Judge, I'll deal with it,
17 but it's going to cost both sides in terms of their time.
18 That's how it works, so --

19 MR. DELINSKY: Your Honor, could we appear
17:18:03 20 at 8:50 on that? I think I can say my peace in 90
21 seconds.

22 THE COURT: I said I'll come out at 8:45
23 and deal with exhibits, and maybe this --

24 MR. DELINSKY: Okay.

17:18:15 25 THE COURT: -- and whatever, but if it goes

1 past 9:00 o'clock, it goes past 9:00 o'clock. I'm not
2 going to cut it off if I've got to deal with it for this
3 person's testimony.

4 MR. MAJORAS: Thank you, Your Honor.

17:18:27 5 MR. DELINSKY: Thank you, Your Honor.

6 MR. STOFFELMAYR: Judge, I have one
7 question, and I think not controversial, because this
8 hasn't come up yet.

9 Tomorrow after Mr. Rannazzisi plaintiffs
17:18:34 10 are calling adversely a retired Walgreen's employee.

11 He's local and he's been subpoenaed.

12 THE COURT: Who is this?

13 MR. STOFFELMAYR: His name is Brian Joyce.

14 He'll be the next witness, we understand.

17:18:44 15 THE COURT: Well, I thought it may be
16 Ashley. I don't know what the order is.

17 MR. STOFFELMAYR: Well, regardless of
18 whether he testifies tomorrow or the day after, I just
19 wanted to confirm that because he's retired and coming
17:18:55 20 pursuant to subpoena we'll have some leeway in our
21 examination if it goes beyond the strict bounds of the
22 direct examination.

23 THE COURT: Well, Mr. Stoffelmayr, you're
24 free, if you want to put in what would be direct now -- I
17:19:07 25 mean now, after his examination -- you're free to.

1 MR. STOFFELMAYR: Thank you.

2 THE COURT: If you want to recall him,
3 that's your call.

4 MR. STOFFELMAYR: Understood. Thank you.

17:19:15 5 THE COURT: As happened with the first
6 witness, I don't know if Mr. Delinsky wants to recall
7 that witness in the CVS case. He's free to do it because
8 he didn't do any real -- you know, it was one question.

9 So that's -- I'm not telling anyone how to
17:19:31 10 try their case.

11 MR. STOFFELMAYR: Thank you. Understood.

12 THE COURT: Okay. See everyone tomorrow
13 morning.

14 Oh, I guess there was, I think, three hours
17:19:41 15 for the defendants and I have 3.25 for the plaintiffs.

16 Okay. See you tomorrow.

17 (Proceedings concluded at 5:19 p.m.)

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C E R T I F I C A T E

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/Susan Trischan

/S/ Susan Trischan, Official Court Reporter
Certified Realtime Reporter

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